Supreme Court, U.S.
FILED
DEC 2 1992
OFFICE OF THE CLERK

No. 92-102

IN THE
Supreme Court of the United States

October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, INDIVIDUALLY AND AS GUARDIANS AD LITEM FOR JASON DAUBERT, AND ANITA DE YOUNG, INDIVIDUALLY AND AS GUARDIAN AD LITEM FOR ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR PETITIONERS

DAVID L. SHAPIRO
1525 Massachusetts Avenue
Cambridge, MA 02138

MICHAEL H. GOTTESMAN
Georgetown Univ. Law Center
600 New Jersey Avenue, N.W.
Washington, D.C. 20001

MARY F. GILLICK
RICHARD S. SPIRRA
LUCE, FORWARD,
HAMILTON & SCRIPPS
600 West Broadway, Suite 2600
San Diego, CA 92101

KENNETH J. CHESEBRO
Counsel of Record
JONATHAN S. MASSEY
1600 Massachusetts Avenue
Cambridge, MA 02138
(617) 661-4423

BARRY J. NACE
PAULSON, NACE, NORWIND
& SELLINGER
1814 "N" Street, N.W.
Washington, D.C. 20036

Counsel for Petitioners

December 2, 1992

BATEMAN & SLADE, INC BOSTON, MASSACHUSETTS

QUESTIONS PRESENTED

1. Whether, in light of the Federal Rules of Evidence, federal courts may apply the rule of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), and hold expert scientific testimony inadmissible unless it has attained general acceptance in the relevant scientific field.

2. Whether the *Frye* rule (assuming its applicability) is properly construed to make the admissibility of expert scientific testimony depend upon prior publication in a peer-reviewed journal.

TABLE OF CONTENTS

QUESTIONS PRESENTED i

TABLE OF AUTHORITIES ii

OPINIONS BELOW 1

JURISDICTION 1

STATUTORY AND CONSTITUTIONAL PROVISIONS . . 1

STATEMENT OF THE CASE 1

SUMMARY OF THE ARGUMENT 14

ARGUMENT

I. THE *FRYE* RULE IS NOT AN AVAILABLE GROUND FOR EXCLUDING SCIENTIFIC EXPERT TESTIMONY UNDER THE FEDERAL RULES OF EVIDENCE . . . 18

A. In Rule 402, Congress Barred Federal Judges From Employing Common-Law Exclusionary Rules That Were Not Authorized or Incorporated by Other Provisions of the Federal Rules of Evidence 19

1. Text 19
2. Legislative History 26

B. The *Frye* Rule Is Not Contained in or Authorized by the Federal Rules of Evidence 28

C. The *Frye* Rule Would Often Be Outcome-Determinative in State-Law Diversity Actions. This Precludes Its Application to Diversity Actions As an Independent Judge-Made Rule, And Confirms That Congress Did Not Intend to to Incorporate It *Into* the Federal Rules of Evidence 41

II. EVEN IF *FRYE* SURVIVES, ITS PROPER APPLICATION CANNOT TURN ON WHETHER THE EXPERT'S OPINION HAS BEEN PREVIOUSLY PUBLISHED IN A PEER-REVIEWED JOURNAL 47

CONCLUSION 50

TABLE OF AUTHORITIES

Cases: **Pages**

Ambrosini v. Labarraque, 966 F.2d 1464 (D.C. Cir. 1992) 36
Barefoot v. Estelle, 463 U.S. 880 (1983) . . . . . *passim*
Barrel of Fun, Inc. v. State Farm Fire & Cas. Co., 739 F.2d 1028 (5th Cir. 1984) 46
Beech Aircraft Corp. v. Rainey, 488 U.S. 153 (1988) . *passim*
Benson v. United States, 146 U.S. 325 (1892) 16, 24
Bernhardt v. Polygraphic Co., 350 U.S. 198 (1956) . . 44, 45
Bourjaily v. United States, 483 U.S. 173 (1987) . . . . *passim*
Busby v. City of Orlando, 931 F.2d 764 (11th Cir. 1991) 33, 39
Byrd v. Blue Ridge Rural Electric Cooperative, Inc., 356 U.S. 525 (1958) 44
Christophersen v. Allied Signal Corp., 939 F.2d 1106 (5th Cir.) (per curiam), *cert. denied*, 112 S. Ct. 1280 (1991) 14, 18, 33
Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992) 45
DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941 (3d Cir. 1990) . . . . . *passim*
Douglass v. Hustler Magazine, Inc., 769 F.2d 1128 (7th Cir. 1985), *cert. denied*, 475 U.S. 1094 (1986) 33
Elkins v. United States, 364 U.S. 206 (1960) 24
Erie R. Co. v. Tompkins, 304 U.S. 64 (1938) . . . . . *passim*
First National Bank of Kenosha v. United States, 763 F.2d 891 (7th Cir. 1985) 36
Frye v. United States, 293 F. 1013 (D.C. Cir. 1923) . *passim*
Garcia v. San Antonio Metropolitan Transit Authority, 469 U.S. 528 (1985) 45
Green v. Bock Laundry Machine Co., 490 U.S. 504 (1989) 21
Gregory v. Ashcroft, 111 S. Ct. 1069 (1991) 45
Guaranty Trust Co. v. York, 326 U.S. 99 (1945) 44

TABLE OF AUTHORITIES (cont.)

Cases: **Pages**

Hanna v. Plumer, 380 U.S. 460 (1965) 44, 45
Hawkins v. United States, 358 U.S. 74 (1958) 24
Heckler v. Chaney, 470 U.S. 821 (1985) 23
Huddleston v. United States, 485 U.S. 681 (1988) 20
Joint Anti-Fascist Committee v. McGrath, 341 U.S. 123 (1951) 49
Mannino v. International Manufacturing Co., 650 F.2d 846 (6th Cir. 1981) 36
McCleery v. City of Bakersfield, 170 Cal.App.3d 1059 (1985) 44
Mistretta v. United States, 488 U.S. 361 (1989) 49
Moragne v. States Marine Lines, Inc., 398 U.S. 375 (1970) 23
Norfolk Redev. and Housing Auth. v. Cesapeake & Potomac Tel. Co., 464 U.S. 30 (1983) 23
Oxendine v. Merrell-Dow Pharmaceuticals, Inc., 506 A.2d 1100 (D.C. App. 1986) 42, 43, 44
People v. Cegers, 9 Cal.Rptr. 297 (1992) 44
Palmer v. Hoffman, 318 U.S. 109 (1943) 44, 45
People v. Kelly, 549 P.2d 1240 (Cal. Supreme Ct. 1976) 43
People v. McDonald, 690 P.2d 709 (Cal. Supreme Ct. 1984) 43, 44
People v. Pitts, 223 Cal.App.3d 606 (1990) 44
People v. Stoll, 783 P.2d 698 (Cal. Supreme Ct. 1989) 43
Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947) 45
Rosen v. United States, 245 U.S. 467 (1918) 16
Salve Regina College v. Russell, 111 S. Ct. 1217 (1991) 50
Siler v. Louisville & Nashville R. Co., 213 U.S. 175 (1909) 49

TABLE OF AUTHORITIES (cont.)

Cases: **Pages**

Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1977), *cert. denied*, 476 U.S. 1104 (1986) 46
United States v. Abel, 469 U.S. 45 (1984) 22, 23, 24
United States v. Baller, 519 F.2d 463 (4th Cir.), *cert. denied*, 423 U.S. 1019 (1975) 18
United States v. Caceres, 440 U.S. 741 (1979) 25
United States v. Christophe, 833 F.2d 1296 (9th Cir. 1987) 31
United States v. Jacobs, 547 F.2d 772 (2d Cir. 1976), *cert. dismissed as improvidently granted*, 436 U.S. 31 (1978) 26
United States v. Jakobetz, 955 F.2d 786 (2d Cir.), *cert. denied*, 112 S. Ct. --- (1992) 17
United States v. Kail, 804 F.2d 441 (8th Cir. 1986) 36
United States v. Kilgus, 571 F.2d 508 (9th Cir. 1978) . . . 12
United States v. Kozminski, 821 F.2d 1186 (6th Cir. 1987), *aff'd in part on other grounds, and remanded in part*, 487 U.S. 931 (1988) 31
United States v. Metzger, 778 F.2d 1195 (6th Cir. 1985), *cert. denied*, 477 U.S. 906 (1986) 18
United States v. Mount, 757 F.2d 1315 (1985) 26
United States v. Onumonu, 967 F.2d 782 (2nd Cir. 1992) 33
United States v. Owens, 484 U.S. 554 (1988) 20
United States v. Payner, 447 U.S. 727 (1980) 25
United States v. Rivera Rodriguez, 808 F.2d 886 (1st Cir. 1986) 33
United States v. Rogers, 918 F.2d 207 (D.C. Cir. 1990) 20
United States v. Salerno, 112 S. Ct. 2503 (1992) 20
United States v. Shorter, 809 F.2d 54 (D.C. Cir.), *cert. denied*, 484 U.S. 817 (1987) 18
United States v. Smith, 869 F.2d 348 (7th Cir. 1989) . . . 18

TABLE OF AUTHOKITIES (cont.)

Cases: **Pages**

United States v. Two Bulls, 918 F.2d 56, (8th Cir. 1990), *reh'g denied, vacated*, 925 F.2d 1127 (8th Cir. 1991) (*en banc*) 18, 31
United States v. Unruh, 855 F.2d 1363 (9th Cir. 1988), *cert. denied sub nom. Forde v. United States*, 488 U.S. 974 (1988) 36
United States v. Wright, 783 F.2d 1091 (D.C. Cir. 1986) 36
United States v. Zolin, 491 U.S. 554 (1989), *cert. denied, sub nom. Church of Scientology v. United States*, 111 S. Ct. 1309 . . . . . 21, 24
Walker v. Armco Steel Corp., 446 U.S. 740 (1980) 45
West v. Conrail, 481 U.S. 35 (1987) 45
Wilder Enterprises v. Allied Artists Pictures, 632 F.2d 1135 (4th Cir. 1980) 33
Wisconsin Public Intervenor v. Mortier, 111 S. Ct. 2476 (1991) 45
Wolfle v. United States, 281 U.S. 7 (1934) 24

Constitutional Provisions, Statutes and Rules: **Pages**

California Evidence Code § 351 . . . . . 27, 28
Federal Rule of Civil Procedure 8(c) 45
Federal Rule of Civil Procedure 42 . . . . . 2, 37, 45
Federal Rule of Criminal Procedure 26 . . . . . 24, 46
Federal Rules of Evidence 104 . . . . . 21, 22
Federal Rules of Evidence 402 . . . . . *passim*
Federal Rules of Evidence 403 . . . . . *passim*
Federal Rules of Evidence 501 . . . . . *passim*
Federal Rules of Evidence 602 36
Federal Rules of Evidence 701 . . . . . *passim*
Federal Rules of Evidence 702 . . . . . *passim*
Federal Rules of Evidence 703 . . . . . *passim*

TABLE OF AUTHORITIES (cont.)

Constitutional Provisions, Statutes and Rules: **Pages**

Federal Rules of Evidence 704 . . . . . *passim*
Federal Rules of Evidence 705 . . . . . *passim*
Federal Rules of Evidence 706 . . . . . *passim*
Federal Rules of Evidence 803(18) 37
Federal Rules of Evidence 803(24) 25
Federal Rules of Evidence 804(b)(5) 25
28 U.S.C. §§ 2071-77 19

Miscellaneous:

Lawrence K. Altman, M.D., *The Doctor's World: Peer Review is Challenged*, N.Y. Times, Feb. 25, 1986, at C3 col. 1 49
Lawrence K. Altman, *Study Says Drug Ads in Medical Journals Frequently Mislead*, N.Y. Times, June 1, 1992, at A1, col. 1 48
Sara Sun Beale, *Reconsidering Supervisory Power in Criminal Cases: Constitutional and Statutory Limits on the Authority of the Federal Courts*, 84 Colum. L. Rev. 1433 (1980) 26
Judge Edward R. Becker & Aviva Orenstein, *The Federal Rules of Evidence After Sixteen Years — The Effect of "Plain Meaning" Jurisprudence, the Need for an Advisory Committee on the Rules of Evidence, and Suggestions for Selective Revision of the Rules*, 60 Geo. Wash.L.Rev. 857 (1992) . . . 20, 21
Margaret Berger, *United States v. Scop: The Common Law Approach to an Expert's Opinion About a Witness's Credibility Still Does Not Work*, 55 Brooklyn L. Rev. 559 (1989) 29

TABLE OF AUTHORITIES (cont.)

Miscellaneous: **Pages**

V. Brannigan, V. Bier, and C. Berg, *Risk, Statistical Inference, and the Law of Evidence: The Use of Epidemiological Data in Toxic Tort Cases*, 12 Risk Analysis 343 (1992) 9
Cleary, *Preliminary Notes on Reading the Rules of Evidence*, 57 Neb. L. Rev. 908, 915 (1978) 23
Federal Rules of Evidence for the United States Courts and Magistrates (West Publishing Co. 1992) . . 19
Paul C. Giannelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States, A Half Century Later*, 80 Colum. L. Rev. 1197 (1980) . . 17
P. Giannelli & E. Imwinkelried, *Scientific Evidence* 13-14 (1986) 17
Gottesman, *Draining the Dismal Swamp: The Case for Federal Choice of Law Statutes*, 80 Georgetown L.J. 1 (1991) 46
Lynne Heckert, *Use of Learned Treatises at Trial, Trial Lawyer's Guide* (1984) 38
Hidden Discord Over Right Therapy, N.Y. Times, Dec. 24, 1991, at B6 col. 1 49
Ladd, *Expert Testimony*, 5 Vand. L. Rev. 414 (1952) . . . 31
L.A. Times, May 22, 1989, Pt. II, at 3 col. 1 48
C. McCormick, *Handbook of the Law of Evidence* § 171 (1954) 17
Charles W. McCutchen, *Peer Review: Treacherous Servant, Disastrous Master*, Technology Review, Oct. 1991 49
A. Mitchell, D. Slone, S. Shapiro & P. Goldman, "Adverse Drug Effects and Drug Surveillance," in Yaffe, *Pediatric Pharmacology* 6
Note, 72 Cornell L. Rev. 620 (1987) 30

TABLE OF AUTHORITIES (cont.)

Miscellaneous: **Pages**

Judge George C. Pratt, *A Judicial Perspective on Opinion Evidence Under the Federal Rules*, 39 Wash. & Lee L. Rev. 313 (1982) 29

S. Rep. No 93-1277, 93rd Cong., 2d Sess. (1974), U.S. Code Cong. & Ad. News 7054 26

Jonathan Schlefer, *Truth, Beauty, and Peer Review*, Technology Review, Oct. 1990 48

Thayer, *Preliminary Treatise of Evidence* 264 (1898) . . . 27

22 Wright & Graham, *Federal Practice and Procedure: Evidence* § 5192 (1978) 27, 28, 41

Judge Jack B. Weinstein, *Improving Expert Testimony*, 20 U. Rich. L. Rev. 473 (1986) 29

Weinstein, *The Uniformity-Conformity Dilemma Facing Draftsmen of Federal Rules of Evidence*, 69 Colum. L. Rev. 353 (1969) 41

Olin Guy Wellborn III, *The Federal Rules of Evidence and the Application of State Law in the Federal Courts*, 55 Tex. L. Rev. 371 (1977) 41, 46

J. Wilson, "Current Status of Teratology," in 1 *Handbook of Teratology* 47 6

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Ninth Circuit is reported at 951 F.2d 1128, and is reprinted at J.A. 237.[1] The memorandum decision and order of the United States District Court for the Southern District of California is reported at 727 F. Supp. 570, and is reprinted at J.A.227.

JURISDICTION

The decision of the Court of Appeals was entered on December 20, 1991. A timely petition for rehearing was denied on April 8, 1992. See J.A. 242. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1). A timely Petition for Writ of Certiorari was granted by the Court on October 13, 1992.

STATUTORY AND CONSTITUTIONAL PROVISIONS

The Federal Rules of Evidence were enacted by Congress in 1975, Pub. L. No. 93-595, 88 Stat. 1926 (1975), 28 U.S.C. app. (1988). Set forth at App. 1-6 to this Brief are the complete text of Rules 104(a) & (b), 401 to 403, 501, 602, 701 to 706, 803(18), 803(24), and 804(b)(5). The complete Advisory Committee's Notes to the Rules and other pertinent legislative history may be found in *Federal Rules of Evidence for the United States Courts and Magistrates* (West Publishing Co. 1992). Set forth at App. 7 are 28 U.S.C. §§ 2071 and 2072, as well as the Rules Enabling Act, 28 U.S.C. § 1652.

STATEMENT OF THE CASE

Petitioners Jason Daubert and Eric Schuller are minor children born with severe and permanent limb-reduction birth defects. They and their parents ("plaintiffs") brought suits for damages in California state court against respondent, Merrell Dow Pharmaceuticals, Inc. ("Merrell"), alleging that the birth defects had been caused by the mothers' ingestion of Bendectin, a prescription anti-nausea drug marketed by Merrell. The complaints alleged exclusively state law causes of action: strict liability, negligence and breach of warranty.

---

[1] Page citations to the Joint Appendix will be styled "J.A.___." Page citations to the Appendix to this Brief will be styled "App. ___."

Merrell removed the lawsuits to federal district court on the basis of diversity of citizenship. Merrell then answered the complaints, denying *inter alia* that the minor plaintiffs' birth defects had been caused by Bendectin. The cases were consolidated for all purposes pursuant to Fed. R. Civ. P. 42.

A. The Summary Judgment Record

After extensive discovery, Merrell moved for summary judgment. Merrell's motion did not contest that the mothers of the minor plaintiffs ingested Bendectin during the critical period of pregnancy in which the limbs of their children were formed. Nor did Merrell's motion suggest that these children had been exposed to any other substances capable of causing limb reductions, or that there were any genetic factors in the family backgrounds that might account for the limb defects.

Rather, the sole ground of the motion was Merrell's claim that "plaintiffs . . . can offer no admissible evidence that proves" that Bendectin causes birth defects.[2] In support of its motion, Merrell submitted an affidavit, two pages in length, of Stephen H. Lamm, a physician and epidemiologist who is President of Consultants in Epidemiology and Occupational Health, Inc.[3] In the affidavit, Dr. Lamm recited that he had reviewed all of the literature on Bendectin and human birth defects. Based upon that literature, and upon his observation that there has been no correlation between "the annual frequency of Bendectin usage and the annual occurrences of specific birth defects," Dr. Lamm concluded "that maternal use of Bendectin during the first trimester in pregnancy is not a risk factor for human birth defects in general, for limb reduction defects specifically, or for any other particular human birth defect." (J.A. 32-33).

Plaintiffs responded to the summary judgment motion by submitting testimony of eight expert witnesses skilled in several relevant scientific and medical disciplines, all of whom disagreed

---

[2] Defendant's Memorandum of Points and Authorities in Support of its Motion for Summary Judgment on the Issue of Causation, at 2.

[3] J.A. 32-33. The affidavit was accompanied by a several-page curriculum vitae of Dr. Lamm establishing his credentials to offer expert opinion testimony on the issue of causation. J.A. 34-44.

with Dr. Lamm's conclusion and reasoning.[4] In addition, plaintiffs submitted six volumes of exhibits, containing trial and deposition testimony of other experts in other cases together with documentary material supportive of their experts' testimony (such as excerpts from scientific text books on teratology and epidemiology).

The experts whose opinions plaintiffs proffered have outstanding credentials, and hold important positions in their fields.[5] These

---

[4] Affidavits were submitted from six of the expert witnesses (J.A. 53-60, 61-66, 73-80, 112-17, 148-53, 187-92), supplemented in the case of four by testimony they had given in other Bendectin cases (Attachment to Daubert/Schuller Opposition to Summary Judgment, Tabs 12 (Swan), 21 (Newman), 26 (Gross), 32 (Glasser)). [Throughout this brief, citations to the materials compiled in the attachment to the summary judgment opposition will be cited simply as "Tab __"] The opinions of the other two experts were proffered via transcripts of their testimony in other cases (Tabs 20 (Snodgrass), 31 (Done)).

[5] Shanna Swan, who received a masters in biostatistics from Columbia and a PhD in statistics from the University of California at Berkeley, is chief of the section of the California Department of Health and Services that determines causes of birth defects. Dr. Swan has also served as a consultant to the World Health Organization, the Food and Drug Administration and the National Institute of Health. J.A. 113-14, 131-32.

Jay Glasser, who received a masters in biostatistics at Columbia and a Ph.D. in experimental statistics at North Carolina State, is a professor of epidemiology at the University of Texas and is serving as court-appointed expert on causation issues in the Dalkon Shield litigation. J.A. 148-49.

Adrian Gross, DVM, a veterinary pathologist, has been employed continuously since 1964 by the Food and Drug Administration and the Environmental Protection Agency in such positions as Chief of Pharmacology at the FDA and Chief of Toxicology at the EPA (in both agencies his responsibility involving determination whether drugs and chemicals cause toxic effects); currently, he is Senior Science Advisor to the EPA and is also consulted by the FDA on causation issues. J.A. 74-76, 85-89; Tab 26 at 850-52.

Stewart Newman, who received his masters and Ph.D. in chemistry from Columbia and the University of Chicago respectively, is a professor at New York Medical College and has devoted more than 15 years to research on the effect of chemicals upon limb development. J.A. 54-56; Tab 21, pp. 186, 196-201. Dr. Newman's work was featured in a *Newsweek* cover story in 1982 describing embryology as the frontier area in biological research. Id.; Tab 35 (Newman) at 370.

See also J.A. 62-63 (Frederick Crescitelli); J.A. 188-90 (John Palmer); Tab 18 (curriculum vitae) and Tab 20 at 2 (Wayne Snodgrass); Tab 18 (curriculum vitae of Allan Done).

experts all concluded that Bendectin[6] is a human teratogen (i.e., a substance capable of causing malformations in human fetuses), and that when ingested at the normal therapeutic dose during the period of pregnancy in which limbs are forming, Bendectin is capable of producing limb defects in human fetuses.[7] Dr. Palmer further concluded that, taking account of Bendectin's teratogenic properties respecting human limbs, the timing of its ingestion by the mothers of the two minor plaintiffs (i.e., during the period of limb formation in the fetus), and the absence in their medical records of any other factor that might explain the birth defects, Bendectin was in fact the cause of the limb reductions suffered by the minor plaintiffs in this case.[8]

In explaining the bases for these conclusions, the experts' affidavits (corroborated by the other materials submitted by plaintiffs in opposition to the summary judgment motion) establish the following subsidiary propositions.

1. The Types of Data Relied Upon By Plaintiffs' Experts and By Scientists Generally in Forming Conclusions as to Whether Human Birth Defects Are Caused by a Suspected Toxin

The experts based their conclusions respecting causation upon an analysis of four sources of information:

(a) "in vivo" animal studies (comparing the offspring of animals subjected to dosages of Bendectin during pregnancy with the offspring of those not subjected to Bendectin);

(b) "in vitro" studies (microscopic examination of animal cells exposed to Bendectin, to determine whether abnormal cell development associated with human limb birth defects results);

(c) pharmacological studies, which examine the chemical structure of Bendectin (and, particularly, of its antihistaminic

---

[6] In some instances, the expert opinion was more precise, identifying the teratogenic agent as the antihistaminic component of Bendectin, called doxylamine succinate.

[7] J.A. 56-60, 63-65, 77-80, 116-17, 152, 191-92; Snodgrass, Tab 20, at 82.

[8] J.A. 192.

component) and compare that structure with the structures of other similar substances known to cause comparable birth defects in humans; and

(d) epidemiological studies (data gathered in studies comparing the incidence of birth defects of various types in the offspring of women who took Bendectin during pregnancy with those of women who did not).

The experts' affidavits submitted by plaintiffs recite that these four sources of information are the standard sources consulted by scientists generally when attempting to form opinions about whether a substance is causing birth defects.[9] Plaintiffs also submitted, in their opposition to the summary judgment motion, the testimony of numerous experts *called by Merrell* in other litigation, agreeing that conclusions respecting causation are customarily predicated upon the results of all four of these sources (and not merely upon the results of epidemiological studies).[10] For example, Merrell's Vice President of Drug Safety Assessment, himself a veterinary pathologist, has testified that the reason Merrell does animal studies is so that "from the data derived [therefrom]" scientists can "make a judgment of predictive value in human beings." (J.A. 109, 111). Even Dr. Lamm, the author of the sole affidavit submitted by Merrell below, has testified elsewhere that all four sources (and not merely epidemiological data) are helpful in determining whether Bendectin causes human birth defects. (J.A. 46-47). The Food and Drug Administration and the Environmental Protection Agency rely upon all four sources in determining causation,[11] and a study published by the congressional Office of Technology Assessment explains why it is "necessary" to consult these sources and not rely solely on epidemiological data.[12]

---

[9] J.A. 56-60, 76-79, 115-17, 191; Tab 20, p. 14; Done, Tab 31, p. 565.

[10] Jones, Tab 7, p. 2664; Seltzer, Tab 11, pp. 2553-54; Luthy, Tab 15, p.30; Shepard, Tab 17, pp. 3645-46; Skalko, Tab 29, pp. 28-29; Scott, Tab 30, p. 1988; and see sources cited next in text.

[11] J.A. 106-07; Gross, Tab 26, pp. 817-18, 847-49; Jones, Tab 7, p. 2664.

[12] J.A. 209.

The scientific discipline that employs these four data sources is known as teratology — the study of non-genetic causes of birth defects.[13] It became important as a field after the Thalidomide experience of 1961, which exploded the assumptions, until then widely shared by biologists and doctors, that all birth defects were genetically determined and that substances ingested by the mother could not harm the fetus because "the mammalian embryo developed within the virtually impervious shelter of the uterus and the maternal body where it was protected from extrinsic factors."[14] Scientists now realized that some substances could pass through the placenta and reach the developing fetus.[15] Although more has been learned since 1961, the field remains one in which scientific advances continue to be made.[16]

2. The Experts' Conclusions Based Upon That Data

In the instant case, plaintiffs' experts concluded, from the following data considered collectively, that there is a causal link between Bendectin and human limb reduction birth defects.

(a) In vivo animal studies have demonstrated overwhelmingly that Bendectin causes limb reductions and other birth defects in a variety of animals that have been tested.[17] In general, animal studies such as these have "good predictive value for humans."[18]

(b) In vitro animal studies have confirmed that Bendectin causes damage and destruction of the cells that are responsible for limb

[13] Tab 21, p. 210 (Newman).

[14] Tab 6, J. Wilson, "Current Status of Teratology,'" in 1 *Handbook of Teratology* 47 (Tab 6, p.47).

[15] J.A. 63.

[16] Wilson, supra, Tab 6, at 49, 60; A. Mitchell, D. Slone, S. Shapiro & P. Goldman, "Adverse Drug Effects and Drug Surveillance", in Yaffe, *Pediatric Pharmacology*, Tab 8, p. 65 [hereinafter, Yaffe Tab 8].

[17] J.A. 76-79; Gross, Tab 26 at 720-22, 796-802, 807-11, 829-34. Indeed, a federal agency has identified Bendectin as a "developmental toxicant" (i.e., a teratogen) in animals. Gross, Tab 26, at 900-04.

[18] J.A. 209 (Office of Technology Assessment report).

formation in the fetus, another predictor of risk for humans.[19]

(c) Chemical structure analyses reveal that the antihistaminic component of Bendectin is similar in structure to that of other antihistamines known to cause limb reduction birth defects when ingested at the critical stage of fetal limb formation.[20]

(d) Epidemiological studies performed on humans prior to Bendectin's withdrawal from the market in 1983 showed a higher incidence of limb reductions in babies born of Bendectin-using mothers than in other babies,[21] although the epidemiologists who had conducted those studies had regarded the results as inconclusive because they fell short of proving an association between Bendectin and limb reductions to the 95% confidence level those epidemiologists had chosen as the measure of "statistical significance."[22]

(e) The epidemiologists conducting those studies had found statistically significant associations (at the 95% confidence level) between Bendectin and three other human birth defects,[23] and as teratogens that damage developing cells tend to leave multiple abnormalities,[24] these findings strengthen the inference to be drawn from the raw data indicating a link to limb reduction as well.[25]

[19] J.A. 57-59; Newman, Tab 21, pp. 258-94.

[20] Newman, Tab 21, pp. 233-58. It is a "basic precept of biology" that organisms are most susceptible to change while they are in the formative stage, and this is especially true of change in the form of growth retardation. The "critical period" is the period of pregnancy when the organ in question is forming. Wilson, Tab 6 at 50-52, 58. In the case of human limbs, the critical period is the fourth to eighth week following conception. Newman, Tab 21 at 214-27.

[21] J.A. 151-52; Glasser, Tab 32 at 132-41, 145-48.

[22] As explained *infra*, pp. 9-10, n.33, limb reduction is a very uncommon occurrence, and as a result studies will not yield statistical significance at the 95% confidence level unless populations larger than those in the Bendectin studies are followed.

[23] Glasser, Tab 32 at 104-14.

[24] Gross, Tab 26 at 768.

[25] Glass, Tab 32, at 133-34.

3. The Areas of Scientific Disagreement

The crux of the disagreement between Merrell's experts and those whose testimony is put forward by plaintiffs is that the latter are prepared to find causation more probable than not when the epidemiological evidence is strongly positive (albeit not at a 95% confidence level) and when it is buttressed with animal and chemical evidence predictive of causation, while the former are unwilling to find causation in the absence of an epidemiological study that satisfies the 95% confidence level. Merrell's position, articulated in its reply to plaintiffs' opposition to the summary judgment motion, was that evidence of causation is inadmissible unless it includes a "published epidemiological study performed on Bendectin which shows a statistically significant causal association between Bendectin and the incidence of limb reduction defects in humans."[26]

At the root of the disagreement between the experts proffered by plaintiffs and by Merrell are two hotly-disputed points. The first relates to the degree of confidence that should be demanded of epidemiological studies before concluding that there is causation in the torts context; the second relates to the integration of epidemiological evidence with the animal/chemical "hard science" evidence.

(a) Statistical experiments assume a "null hypothesis" (i.e. that the factor under study is not a cause of the results to be observed) and then ask whether the observable data depart from that hypothesis. In a study of a chemical's propensity, for example, there will be two groups studied, one that ingested the chemical and one that did not. If the null hypothesis is true (i.e. the chemical does not cause human defects) the two groups should show no difference in the incidence of defects.[27] But, of course, even when the null hypothesis is true, in nature there are random events that will skew the data. Accordingly, scientists are cautious about drawing conclusions respecting causation simply because the observable data show some variation from the null hypothesis.

---

[26] Defendant's Reply to Plaintiffs' Opposition to Defendant's Motion for Summary Judgment, p. 2.

[27] K. Rothman, *Modern Epidemiology* (Tab 9), at pp. 116-17.

In their quest for certainty, scientists have conventionally insisted upon a very high threshold of confidence before being willing to declare truths from statistical evidence; in the absence of that degree of confidence, scientists prefer to declare the results inconclusive and continue their search. To this end, an "arbitrary point . . . is selected," usually one that requires 95% confidence that the skew is not the result of randomness.[28] Under this approach, a statistical result is not deemed "significant" unless the data are such that there is less than one chance in twenty that the data would skew so far and yet the null hypothesis still be true. In this manner, the risk of "Type I" error — the risk that a false-positive correlation will be found (here, of causation) — is kept below 5%.[29]

But in toxic tort lawsuits, the issue is not whether it is certain that a chemical caused a result, but rather whether it is "likelier than not" that it did. It is not self-evident that the latter conclusion would require eliminating the null hypothesis (i.e. non-causation) to a confidence level of 95%.[30] And, indeed, to insist upon such a high level of confidence is to risk a much greater error in the other direction — a "Type II" or "false-negative" error: that causation will not be found although in fact it is occurring.[31] Dr. Swan calculated the risk of Type II error from the Bendectin studies and found, as to each study, that *even if Bendectin were causing a doubling of the incidence of human limb reductions* there was less

---

[28] Rothman, supra, Tab 9 at 116.

[29] Yaffe, Tab 8, at p. 68; Rothman, Tab 9, at pp. 115-17. Of course, as these textbooks emphasize, the fact that statistical data fall short of showing an association at the 95% level is not evidence that proves the *absence* of causation. Yaffe, Tab 8 at 69; Rothman, Tab 9 at 116-17. *A fortiori*, it cannot be evidence of non-causation when, as here, the data show a positive correlation.

[30] This is a point that many scientists have been attempting to communicate to lawyers, most recently in an article that explains the error in dismissing the epidemiological evidence respecting Bendectin as non-probative. V. Brannigan, V. Bier, and C. Berg, "Risk, Statistical Inference, and the Law of Evidence: The Use of Epidemiological Data in Toxic Tort Cases, 12 Risk Analysis 343 (1992). See also, Rothman, Tab 9, at 117-18 (criticizing the importance attached to significance at the 95% confidence level.)

[31] Yaffe, Tab 8, at p. 69; Rothman, Tab 9, at pp. 117-18.

than a 20% chance that the study would yield a "statistically significant" outcome if "significance" was defined as confidence at the 95% level.[32] This is because epidemiological studies are unlikely to detect (at a 95% confidence level) adverse reactions, such as limb reduction, that are experienced by only a small percentage of the population.[33] In other words, to require a 95% confidence showing would be to protect against a 5% risk of erroneously finding causation when it is not present, *while creating a greater than 80% risk that true causation doubling the incidence of harm would go undetected.*

The epidemiological studies of Bendectin showed a higher relative incidence of birth defects among the offspring of mothers who ingested Bendectin than among those who did not.[34] But the populations covered in the studies were not large enough to allow a finding of causation with the level of "statistical significance" set at 95%.[35] The data would, however, allow a finding that causation is far likelier than not, albeit at confidence levels somewhat below 95%.[36]

---

[32] Swan, Tab 12, at pp. 3578, 3597-98.

[33] Yaffe, Tab 8, at 65, 69, 71-72 (even adverse reactions affecting 1 in 100 of those tested are not likely to yield statistical significance at a 95% confidence level); Swan, J.A. 116; Tab 12 at 3568 (limb reductions affect less than 1 in 1,000); Glasser, Tab 32 at 30-32, 77-80.

[34] *See* p. 7, *supra*. Statisticians define the "relative risk" as the rate of occurrence in the exposed group (here, mothers taking Bendectin at the critical period) divided by the rate of occurrence in the nonexposed group. Yaffe, Tab 8, at 68. If 2% of the users of the substance being studied give birth to children with birth defects, but only 1% of those not using the substance, the relative risk would be 2.0 (2% divided by 1%).

[35] Swan, Tab 12 at 3600; Glasser, Tab 32 at 134-41, 145-48. *See also* p. 10 n.33, *supra*.

[36] An alternative mechanism has been developed by epidemiologists in recent years to give a somewhat more informative picture of what the statistics mean. At any given confidence level (e.g. 95%) a "confidence interval" can be constructed. The confidence interval identifies the range of relative risks that collectively comprise the 95% universe. Additional confidence levels are then constructed exhibiting the range at other confidence levels, e.g., at 90%, 80%, etc. From this set of "nested confidence intervals" the epidemiologist can make assessments of how

(b) The second source of dispute among experts relates to the integration of epidemiological data with the animal and chemical data. Some experts, while acknowledging that animal and chemical studies can point in the direction of causation, are unwilling on that account to reduce the confidence level required of epidemiological evidence before it will convince them of causation. Plaintiffs' experts, by contrast, have testified that it is appropriate to consider the combined weight of the animal, chemical and epidemiological evidence, and to accept epidemiological evidence as indicative of causation at a lower confidence level when it is buttressed by animal and chemical evidence strongly suggesting causation.

Plaintiffs' experts testified that this latter approach is particularly appropriate when, as they explained was the case here, the epidemiological studies (whether because of methodological flaws[37] or insufficient sample size[38]) were unlikely to detect a positive association of the drug with birth defects even if the association

---

likely it is that the statistics are showing a true association. Rothman, Tab 9, pp. 122-25. By calculating nested confidence intervals for the data in the Bendectin studies, Dr. Swan was able to determine that it is far more likely than not that a true association exists between Bendectin and human limb reduction birth defects. Swan, Tab 12, at 3618-28.

[37] Dr. Swan testified at length describing the methodological flaws in the Bendectin studies that were conducted prior to its removal from the market, virtually all of which had the effect of *understating* the degree of association between Bendectin users and limb reduction birth defects. Swan, Tab 12, at 3600-18, 3649-55. Among the flaws she described were, e.g., lumping limb reductions together with other limb defects in the reporting (since limb reductions occur only one-tenth as often as other limb defects, the effect was to dwarf entirely the ability to detect the association relevant to this case); including women who first ingested Bendectin after their eighth week of pregnancy in the Bendectin-user group, rather than the control group (since the limbs of the fetus are formed after eight weeks, Bendectin could no longer harm them; including them on the wrong side of the equation skewed both numbers against association); including in the control group mothers taking other antihistamines (since some antihistamines are known to cause limb reduction birth defects, the effect was to increase the risk of birth defects on the non-Bendectin side of the equation, but on grounds that do not rule out the toxic effect of Bendectin). *Id*. See also Glasser, Tab 32 at 119-26, 129.

[38] Swan, Tab 12, at 3600. *See also* p. 10 n.33, *supra*.

existed.[39]

B. The District Court's Opinion

On the basis of the record just described, the district court granted summary judgment to Merrell and dismissed the complaints. The court explained that it "should exclude inadmissible evidence objected to by either party prior to ruling upon the motion." (J.A. 229). From that unassailable starting point, the court leapt to the more controversial one that is the focus of the issue before this court: "A necessary predicate to the admission of scientific evidence is that the principle upon which it is based 'must be sufficiently established to have general acceptance in the field to which it belongs.'" (*id.*, citing *United States v. Kilgus*, 571 F.2d 508, 510 (9th Cir. 1978)). Although the district court did not cite the *Frye* case, this is the *Frye* rule.[40]

The court then proceeded to apply that rule to this case. While there are "two schools of thought governing expert testimony in these Bendectin cases," the school that "seems to be prevailing in the federal courts" is that "causation may be shown only through reliance upon epidemiological evidence." (J.A. 229-30). What is more, only epidemiological evidence that is "statistically significant" may be used to prove causation. (J.A. 235). The experts' testimony proffered by plaintiffs did not, in the district court's view, meet this profile.[41] Accordingly, summary judgment was granted in favor of defendants on all causes of action. (Pet. J.A. 236).

---

[39] Their position on this point is bolstered by the report of the congressional Office of Technology Assessment, confirming the difficulties of securing meaningful results from epidemiological data and citing those difficulties as a reason why animal studies are "necessary." J.A. 209.

[40] While the district court did not cite *Frye*, the *Kilgus* opinion from which it quoted the rule cited *Frye* as its source. The district court apparently believed that the *Frye* rule is dictated by Rule 703 of the Federal Rules of Evidence (J.A. 229), although *Kilgus* did not mention the Federal Rules of Evidence and appears to have assumed that the *Frye* rule exists independently of the Federal Rules of Evidence. In the argument, petitioners address both whether the *Frye* rule can stand independently and, if not, whether it is a proper interpretation of Rule 703.

[41] The district court did not explain what it believed constituted statistical significance, but a review of the cases it cited indicates that it understood the term to require a showing that satisfied the 95% confidence level.

C. The Court of Appeals' Opinion

The court of appeals agreed that the testimony of the experts proffered by plaintiffs was inadmissible. "Expert opinion based on a scientific technique 'is admissible if it is generally accepted as a reliable technique among the scientific community'" (J.A. 238 (citing *Frye*)) Whether expert testimony satisfies this requirement "is reviewed *de novo* by [the] appellate court," because "the reliability of a scientific technique or process does not vary according to the circumstances of each case" and thus cannot appropriately be left "within each trial judge's individual discretion." (J.A. 238-39).

"For expert opinion based on a given scientific methodology to be admissible, the methodology cannot diverge significantly from the procedures accepted by recognized authorities in the field." (J.A. 239). The court explained that expert testimony of causation will not be admissible if it is not supported by epidemiological studies. (J.A. 239-40). Although plaintiffs' experts rested their conclusions in part upon a reanalysis of epidemiological studies, the court held that "reanalysis of epidemiological studies is generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field." (J.A. 240). "Plaintiffs' reanalyses do not comply with this standard; they were unpublished, not subjected to the normal peer review process, and generated solely for use in litigation." (J.A. 240-41). The court concluded:

> [W]e agree with the district court that the available animal and chemical studies, together with plaintiffs' expert reanalysis of epidemiological studies, provide insufficient foundation to allow admission of expert testimony to the effect that Bendectin caused plaintiffs' injuries. Accordingly, plaintiffs could not satisfy their burden of proving causation at trial . . . . "When the contested evidence is essential to the cause of action and the trial court has excluded the evidence, we may decide the appeal . . . solely on the basis of the soundness of the evidentiary ruling. For if we uphold the exclusion of essential evidence, the [review of the summary judgment ruling] becomes academic."

J.A. 241 (brackets in opinion).[42]

On October 13, 1992, this Court granted certiorari. 113 S. Ct. 320 (1992).

SUMMARY OF THE ARGUMENT

The central issue in this case is whether the rule of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) — that expert scientific opinion evidence is inadmissible unless it has attained general acceptance in the relevant scientific field — survived the enactment of the Federal Rules of Evidence in 1975.

1. *Frye* cannot stand as a judge-made rule of evidence independent of the Federal Rules. Rule 402 declares that "all relevant evidence is admissible except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority." The failure to list judge-made rules in the exception is conspicuous, and it was not inadvertent. Congress wanted to broaden the admissibility of evidence, and to that end it "wiped the slate clean" with Rule 402 and then adopted expressly those of the common-law rules for excluding evidence that it wished to retain. In the one instance where Congress decided to leave room for further judicial elaboration of exclusionary rules — the area of privileges — Congress expressly so provided (see Rule 501).

2. Thus *Frye* survives only if it was incorporated into the Federal Rules in 1975. But there is not a word in the Rules as enacted, nor in the Advisory Committee's Notes or legislative history, suggesting that Congress adopted *Frye* (or any other "general acceptance" requirement for expert testimony) as an exception to Rule 402's broad declaration of admissibility.

This is not surprising, for the Rules follow the "general approach of relaxing the traditional barriers to 'opinion' testimony." *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988), and *Frye* had been widely condemned by leading evidence commentators

---

[42] Quoting from *Christophersen v. Allied-Signal Corp.*, 939 F. 2d 1106, 1109 (5th Cir.) (en banc), *cert. denied*, 112 S. Ct. 1991).

as unduly restrictive of expert testimony. Congress chose to rely instead upon the adversarial process to expose the deficiencies of experts' opinions, and entrusted to juries the task of determining which parties' experts deserved credence. *Id.* at 168; *Barefoot v. Estelle*, 463 U.S. 880, 898, 900-02 & n.8 (1983). And, to address the problem of "venal" experts, Congress empowered federal judges in rule 706(a) to appoint neutral experts who could explain the state of scientific understanding respecting the subject at issue.

Proponents of *Frye* have sought to locate it in the entirely different wording of Rules 702 or 703, but those provisions plainly do not embrace it. Rule 702 merely declares that qualified experts can present opinions whenever the situation is a proper one for expert testimony (i.e., whenever the trier of fact would benefit form receiving specialized knowledge); Rule 702 does not empower judges to evaluate the quality of the opinion the expert witness will render or to exclude opinions that have not achieved general acceptance.

Rule 703 relieves experts of the common law stricture of having to base their opinions solely upon data that has been admitted into evidence, and thus enables them to testify on the basis of, e.g., the data in studies done by others. However, such extra-record data may be relied upon without introducing it into evidence only if it is "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." This does not make Rule 703 the *Frye* rule, for two reasons: (1) the "reasonably relied upon" language does not constrain an expert so long as he or she relies upon data that has been admitted into evidence, and (2) often, as here, the data base that the expert relies upon *is* that relied upon generally by scientists in the field. Rule 703 plainly does not empower courts to forbid experts from testifying to the conclusions they have reached from the accepted database simply because their particular conclusions have not themselves attained general acceptance.

3. An additional consideration that militates strongly against the survival of *Frye* is that it would be outcome determinative in state law diversity cases. For example, the evidence that the courts below *would not admit* has been found sufficient *to sustain the plaintiffs' claim* in a Bendectin case litigated under District of Columbia law.

Because Frye is outcome-determinative, this Court's jurisprudence under *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), would doom any effort to sustain it as a judge-made rule that stands independent of the Federal Rules, at least with respect to state law claims. And the *Frye* rule's substantive effect also strengthens the showing that Congress did not incorporate *Frye* into the Federal Rules. For in crafting those rules, Congress took scrupulous care to assure that none would have outcome-determinative effects on state law. Indeed, in three instances where that potential existed, Congress expressly provided that the rule would apply only to federal question suits. If Congress had intended to incorporate *Frye*, it undoubtedly would have made similar provision to protect state law claims.[43]

ARGUMENT

Introduction

This case centers on an evidentiary rule first announced in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). *Frye* was a federal criminal case in which the U.S. Court of Appeals for the D.C. Circuit addressed the admissibility of expert testimony setting forth the results of a "systolic blood pressure deception test," a rudimentary precursor to the modern polygraph. *Id.* at 1013. Exercising its common-law authority to prescribe rules of evidence for federal criminal trials "'in the light of general authority and sound reason,'" *Rosen v. United States*, 245 U.S. 467, 471 (1918) (quoting *Benson v. United States*, 146 U.S. 325, 335 (1892)), the D.C. Circuit announced what has come to be known as the "*Frye* rule" barring evidence derived from novel scientific techniques:

> Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-

[43] We show in Part II that even if *Frye* survives, it was misconstrued by the court below.

> recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.

Id. at 1014.

In the half-century that followed, many federal courts applied the common-law *Frye* rule to determine the admissibility of a variety of novel scientific techniques in criminal trials. Paul C. Giannelli, *The Admissibility of Novel Scientific Evidence:* Frye v. United States, *A Half Century Later*, 80 Colum. L. Rev. 1197, 1199-1200 & nn. 14-16, 1205-06 (1980) (citations omitted) (scrutinized techniques included "voiceprints, neutron activation analysis, gunshot residue tests, bitemark comparisons, sodium pentothal, scanning electronic microscopic analysis, and numerous other forensic techniques"). During that same period, others rejected the rule as overly vague and unduly restrictive in denying juries useful evidence. *See, e.g., id.* at 1206-28; P. Giannelli & E. Imwinkelried, *Scientific Evidence* 13-14 (1986) ("[T]he [*Frye*] general acceptance test has been rejected by an increasing number of courts and attacked by commentators, who have labelled the test 'infamous,' 'a sport,' 'archaic,' and 'antiquated on the day of its pronouncement'"); p. 29 note 59, *infra*. Dean McCormick catalyzed the attack on the *Frye* rule in the first edition of his leading hornbook. C. McCormick, *Handbook of the Law of Evidence* § 171, at 363 (1954) (general acceptance test "is a proper condition upon the court's taking judicial notice of scientific facts, but not a criterion for the admissibility of scientific evidence").

In 1975, Congress enacted the Federal Rules of Evidence. Neither the *Frye* rule nor any other requirement of "general acceptance" appears in the text of the Rules. Nor is there mention of either in the lengthy and public Advisory Committee and congressional proceedings that eventuated in adoption of the Rules. *See* Giannelli, *supra*, at 1229-30.

The federal circuits have disagreed as to whether *Frye* survived the enactment of the Federal Rules of Evidence.[44] The Ninth

[44] Three circuits have said no: *United States v. Jakobetz*, 955 F.2d 786, 794-97 (2d Cir.), *cert. denied*, 61 U.S.L.W. 3257 (1992); *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 955 (3d Cir. 1990); *United States*

Circuit is one of those that has continued to apply *Frye*, and in the instant case it has taken *Frye* far beyond its pre-1975 confines. In this case, it has held *Frye* applicable to *civil* cases — indeed, to civil diversity cases governed by state substantive law whose outcomes will be effectively determined by the exclusion of evidence that the state would regard sufficient to establish the party's claim. This case affords the Court an opportunity to address the current status of *Frye* and, more broadly, to clarify the meaning of critical portions of the Federal Rules of Evidence.

I. THE *FRYE* RULE IS NOT AN AVAILABLE GROUND FOR EXCLUDING SCIENTIFIC EXPERT TESTIMONY UNDER THE FEDERAL RULES OF EVIDENCE

Two arguments have been advanced by proponents of the *Frye* rule to support its continued use. One is that, because the *Frye* rule was never mentioned during the formulation and enactment of the Federal Rules of Evidence, federal judges remain free to apply it as a judge-made rule independent of the Federal Rules of Evidence. The other argument is that one or another of the specific Rules passed by Congress should be construed to contain the *Frye* principle.

Both arguments are refuted by the plain meaning of the Federal Rules of Evidence. We deal first with the contention that the *Frye* rule stands independent of the Federal Rules (Part I-A), for the discussion of that issue establishes statutory guideposts that are also applicable to the contention that *Frye* is hiding camouflaged *in* the Rules (Part I-B). Finally, we address the special problems that are posed because *Frye* is outcome-determinative and, if a federal rule of evidence, would alter the results of state-law diversity actions in ways never intended by Congress.

---

v. Baller, 519 F.2d 463, 466 (4th Cir.), *cert. denied*, 423 U.S. 1019 (1975). Six Circuits have said yes: Ninth Circuit decision below; *Christophersen v. Allied Signal Corp.*, 939 F.2d 1106, 1115-16 (5th Cir.) (per curiam) (en banc), *cert. denied*, 112 S. Ct. 1280 (1991); *United States v. Two Bulls*, 918 F.2d 56, 60 & n.7 (8th Cir. 1990), *reh'g granted, vacated*, 925 F.2d 1127 (8th Cir. 1991) (*en banc*); *United States v. Smith*, 869 F.2d 348, 351 (7th Cir. 1989); *United States v. Shorter*, 809 F.2d 54, 59-61 (D.C. Cir.), *cert. denied*, 484 U.S. 817 (1987); *United States v. Metzger*, 778 F.2d 1195, 1203 (6th Cir. 1985), *cert. denied*, 477 U.S. 906 (1986).

A. In Rule 402, Congress Barred Federal Judges From Employing Common-Law Exclusionary Rules That Were Not Authorized or Incorporated by Other Provisions of the Federal Rules of Evidence

1. Text

The contention that *Frye* survives as a judge-made rule for excluding evidence, merely because it existed for half a century prior to enactment of the Rules, cannot be squared with the plain meaning of the statute. Analysis must begin with the text of Fed. R. Evid. 402, which provides:

> **Rule 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible**
>
> All relevant evidence is admissible, except as otherwise provided by [1] the Constitution of the United States, [2] by Act of Congress, [3] by these rules, or [4] by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

(Brackets added). Rule 402 states unambiguously that "*all* relevant evidence is admissible" subject to enumerated exceptions. Conspicuously, this precise list of exceptions does not provide for exclusion rules created by judges through decisional law. To be sure, this Court is accorded power to enlarge the grounds for exclusion, but the means are clearly stated: "by other rules *prescribed* by the Supreme Court *pursuant to statutory authority*."[45] This refers to the rule-making power in 28 U.S.C. § 2072, and assures that the elaborate procedural requirements and congressional oversight of 28 U.S.C. §§ 2071-77 will precede their

---

[45] Congress added the italicized words to underscore exactly how the Court must proceed; the prior version of Rule 402 promulgated by the Court had used broader language: "by other rules adopted by the Supreme Court." *See* Note (Federal Judicial Center) to Rule 402. *Federal Rules of Evidence for the United States Courts and Magistrates* 26 (West Publishing Co. 1992). As we show in Part I-C, *infra*, Congress injected this limitation to protect state substantive law against erosion caused by judge-made rules of evidence. Congress's use of the word "prescribed" and insertion of the four words "pursuant to statutory authority" renders frivolous any argument that Rule 402 contemplates the courts' exercise of a common-law power to formulate evidentiary standards.

adoption. *See* Judge Edward R. Becker & Aviva Orenstein, *The Federal Rules of Evidence After Sixteen Years — The Effect of "Plain Meaning" Jurisprudence, the Need for an Advisory Committee on the Rules of Evidence, and Suggestions for Selective Revision of the Rules*, 60 Geo. Wash.L.Rev. 857, 858-62 (1992). This statutory scheme would be wholly undermined if the federal courts had power to create and apply additional exclusion rules through decisional law.

The clarity of Rule 402's command should be the end of the matter. This Court has held that the Federal Rules of Evidence are to be interpreted like any other statute. *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163 (1988) ("[b]ecause the Federal Rules of Evidence are a legislative enactment, we turn to the 'traditional tools of statutory construction,' in order to construe their provisions") (citation omitted). *See also United States v. Rogers*, 918 F.2d 207, 209 (D.C. Cir. 1990) (Thomas, J.) (on evidence questions a court must "begin as . . . with any statute, with the language of the rules themselves").

This Court has repeatedly refused to entertain litigants' policy arguments for altering a straightforward reading of the Rules. For example, in *Huddleston v. United States*, 485 U.S. 681, 687-88 (1988), the Court rejected the theory, *id.* at 685 n.2, that where the prosecution produces evidence of "other crimes" for a noncharacter purpose complying with the plain terms of Rule 404(b), the trial judge should engage in independent scrutiny of whether the other crimes occurred. The Court unanimously held that this theory was "inconsistent with the plain language of Rule 404(b)" which contained "no intimation . . . that any preliminary showing is necessary before such [extrinsic act] evidence may be introduced for a proper purpose." *Id.* at 687-88. *See also United States v. Salerno*, 112 S. Ct. 2503, 2507-08 (1992) (refusing to engraft an "implicit limitation[]" to Rule 804(b)(1) despite claims of government abuse of the Rule); *United States v. Owens*, 484 U.S. 554, 561-62 (1988) (finding Rule 801(d)(1)(C)'s "subject to cross-examination" requirement met by witness' mere presence at trial, despite his loss of memory on the issue in question).[46]

---

[46] The *only* circumstances where this Court has declined to apply the plain meaning of the Rules have been those where the result would be arguably unconstitutional or so absurd as to be wholly inconsistent with congressional purpose — canons of construction applicable to legislative interpretation generally. In *Green v. Bock Laundry Machine Co.*, 490 U.S. 504 (1989), this Court found that Fed. R. Evid. 609(a) (concerning impeachment by other crimes), if read literally, would require a weighing of prejudice only against the *defendant* in a civil or criminal case — so that "impeachment detrimental to a civil *plaintiff* always would have to be admitted." *Id.* at 509-10. The Court held that although the imbalance in Rule 609(a) could be justified in the criminal context, the civil context mandated equality between plaintiff and defendant; the Court could not "accept an interpretation that would deny a civil plaintiff the same right to impeach an adversary's testimony that it grants to a civil defendant." *Id.* at 510. *See also id.* at 527 (Scalia, J, concurring in the judgment) ("[w]e are confronted here with a statute which, if interpreted literally, produces an absurd, and perhaps unconstitutional, result," justifying a resort to legislative history "to verify that what seems to us an unthinkable proposition (civil defendants but not civil plaintiffs receive the benefit of weighing prejudice) was indeed unthought-of, and thus to justify a departure from the ordinary meaning of the word 'defendant' in the Rule"); *United States v. Zolin*, 491 U.S. 554, 565-66 (1989) (refusing to read Rules 104(a) and 1101(c), stating that privileges apply in all proceedings, to produce the "absurd result" that the crime-fraud exception to the attorney-client privilege could almost never be proven, because a judge would never have authority to examine relevant documents *in camera*). Receiving scientific expert testimony, if none of the statutory tests governing the evidence is violated, *see* Part I-B, *infra*, does not remotely trigger those exceptions.

Of particular application here, this Court has refused to depart from the plain meaning of the Rules as a means of preserving pre-1975 common-law doctrines inconsistent with language in the Rules. In *Bourjaily v. United States*, 483 U.S. 171 (1987), the Court considered the status of the long-established common-law "bootstrapping rule" under the co-conspirator exception to the hearsay rule. That rule — firmly embraced by the Court itself prior to the Rules' enactment in 1975 — had always barred hearsay statements *themselves* from being used to prove conspiracy and thus to trigger the co-conspirator exception to the prohibition on hearsay. In previous cases, the Court had reasoned that without that rule, "'hearsay would lift itself up by its own bootstraps to the level of competent evidence.'" *Id.* at 177 (citation omitted). In considering whether that rule had survived enactment of the Federal Rules of Evidence, the Court noted Rule 104(a)'s provision that when deciding preliminary facts conditioning the admissibility of evidence, a trial court "is not bound by the rules of evidence except those with respect to privileges." The Court found this plain

language decisive and rejected a contrary argument that the bootstrapping rule should prevail because Congress had not specifically evidenced an intent to discard it:

> [The text of Rule 104(a)] would seem to many to be the end of the matter. Congress has decided that courts may consider hearsay in making these factual determinations.
>
> * * *
>
> [But] [p]etitioner claims that Congress evidenced no desire to disturb the bootstrapping rule, which was embedded in the previous approach, and we should not find that Congress altered the rule without affirmative evidence so indicating. It would be extraordinary to require legislative history to *confirm* the plain meaning of Rule 104.

Id. at 177-78 (emphasis in original).

Bourjaily shows the unsoundness of any contention that rules of exclusion not themselves incorporated into the Federal Rules of Evidence can survive the command of Rule 402. This does not mean, of course, that Congress abandoned all that had gone before. Congress enacted the Federal Rules of Evidence against the backdrop of a long history of common-law development of evidence rules. "Before the present Rules were promulgated, the admissibility of evidence in the federal courts was governed in part by statutes or Rules, and in part by case law." *United States v. Abel*, 469 U.S. 45, 50 (1984). Not surprisingly, Congress chose to incorporate many of these common-law doctrines for excluding evidence into the Rules. However, when it did, it did so explicitly. As the Advisory Committee's Note to Rule 402, ¶ 3, explains, in Article IV and succeeding Rules Congress specifically designated the grounds for excluding or limiting the scope of evidence.

Most of the common-law exclusionary doctrines preserved by the Rules appear in Article IV, entitled "Relevancy and Its Limits." Rules 404 through 412 set out a list of categorical grounds codifying the common-law rules that Congress saw fit to impose as limits on otherwise relevant evidence.[47] Other explicit rules authorizing

[47] As the Advisory Committee's Note states, these statutory exceptions were imposed "in response to the demands of particular policies," that were thought to "require the exclusion of evidence despite its relevancy." Advisory Committee's Note to Rule 402, ¶ 3. These exceptions preserve common-law rules generally barring character evidence to prove conduct but permitting habit evidence (Rules 404 to 406), barring evidence of subsequent remedial measures to prove wrongdoing (Rule 407), barring use of settlement negotiations or payment of medical expenses or existence of insurance to prove liability (Rules 408, 409 and 411), barring use of withdrawn guilty pleas (Rule 410), and generally barring reference to the past sexual behavior of an alleged victim of a sex offense (Rule 412).

exclusion of evidence appear in Rules 501, 704(b), and 801 to 804. In addition to these *per se* exclusion rules, Rule 403 authorizes trial judges to exclude other items of evidence on a case-by-case basis, when a particularistic balancing yields the conclusion that the probative value of the evidence is "substantially outweighed" by danger to the fairness of the trial.

An examination of the text of other provisions of the Federal Rules of Evidence demonstrates that Congress used explicit words when it intended to vest judges with authority to continue to promulgate and apply common-law rules for excluding evidence. Rule 501 states that in federal question cases, *privileges* "shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience."[48] This is the language the federal courts have invoked not only when they are deciding whether to recognize new privileges but also when they are defining the parameters of preexisting common law privileges such as the attorney-client privilege.[49] For example, this Court relied on Rule 501 as

[48] It is noteworthy that Rule 501 does *not* extend federal common-law power to issues involving state-created rights and obligations. *See* Part I-C, *infra*.

[49] Thus, the common-law background can be pertinent to interpreting *ambiguities* in the Rules. *See, e.g., Heckler v. Chaney*, 471 U.S. 821, 832-33 (1985); *Norfolk Redevelopment & Housing Auth. v. Chesapeake & Potomac Tel. Co.*, 464 U.S. 30, 35-36 (1983); *Moragne v. States Marine Lines, Inc.*, 398 U.S. 375, 392 (1970). As the Court explained in *Abel*, endorsing the analysis of Professor Cleary, the Reporter for the Rules:

> "In principle, under the Federal Rules no common law of evidence remains. 'All relevant evidence is admissible, except as otherwise provided . . . .' In reality, of course, the body of common law knowledge continues to exist, though in the somewhat altered form of a source of guidance in the exercise of delegated powers." Cleary, *Preliminary Notes on Reading the Rules of Evidence*, 57 Neb. L. Rev.

authority for its decision in *United States v. Zolin*, 491 U.S. 554, 562 (1989). The language of Rule 501 is striking for its dissimilarity to that in Rule 402 and in the rules specifically addressed to expert opinion (Rules 702 to 706) — none of which contains any authorization for common-law rulemaking. The textual differences become even more significant when the source of Rule 501's language is examined. The "reason and experience" phrase was drawn from the former Fed. R. Crim. P. 26, which had authorized common-law rulemaking with respect to *all* evidence rules in criminal cases. In its Rule 26 form, the language was expansive enough to authorize courts to embrace *Frye* in criminal cases.[50] In shaping the Federal Rules of Evidence, however, Congress opted to carry forward the language *only* with respect to privileges. Nowhere else are the courts left with authority to fashion exclusion rules: everywhere else, rules of exclusion are spelled out explicitly.

908, 915 (1978) (footnote omitted).

469 U.S. at 51-52. For example, in *Abel* the Court unanimously held that the well-recognized ability to impeach for "bias," as the concept is "used in the common law of evidence," could be invoked under the Rules. 469 U.S. at 52. In light of the "state of unanimity" favoring the doctrine under the common law, the Court thought it "unlikely that [the drafters] intended to scuttle entirely the evidentiary availability of cross-examination for bias" — a holding that the Court specifically noted was consistent with Rule 402's requirement that, in general, all relevant evidence is admissible. *Id.* at 50-51.

As *Abel* demonstrates, the wording of Rule 402, creating a presumption of admissibility, obviated any need for Congress to preserve common-law doctrines of *inclusion*, and indeed the Rules do not attempt to do so. By contrast, the plain language of Rule 402 demonstrates that unless Congress preserved or authorized a common-law *exclusion* doctrine in *a specific Rule*, the doctrine cannot be used to exclude evidence.

[50] Federal courts had been creating common-law rules to govern criminal trials "in the light of reason and experience," *Wolfle v. United States*, 281 U.S. 7, 12 (1934), at least since this Court's decision in *Benson v. United States*, 146 U.S. 325, 335 (1892). Congress confirmed this power by incorporating the *Wolfle* language into Fed. R. Crim. P. 26, setting forth common-law authority over criminal evidence law. *Hawkins v. United States*, 358 U.S. 74, 76 (1958). Under Rule 26 as it existed before 1975, federal courts were free to fashion common-law evidence rules for criminal cases as long as they were consistent with the Federal Rules of Criminal Procedure and congressional statutes. *Elkins v. United States*, 364 U.S. 206, 216 (1960).

The intent to limit judicial creativity is further evidenced by the words Congress chose in Article VIII dealing with hearsay. Congress enacted a general ban on hearsay (Rule 802), together with 29 exceptions (Rules 803 and 804). The courts are allowed to fashion additional grounds for exception from the hearsay ban on an *ad hoc* basis in "catchall" provisions, Rules 803(24) and 804(b)(5), but the criteria for exercising that power are spelled out expressly in these rules.[51] The specificity with which Congress allowed some room for judicial creativity in Article VIII underscores again the significance of the total *absence* of any similar language either in Rule 402 (the general provision directing admission of relevant evidence) or in Rules 702 to 706 (the provisions governing expert opinion testimony, *see* Part I-B, *infra*).

In sum, the plain terms of Rule 402 and of Rules 702 through 706 bar any use of judge-made rules for excluding opinion evidence. If Congress had wished to leave room for judicial expansion upon its work, it would have expressly so provided, as it did in Rules 501, 803(24) and 804(b)(5). Under this carefully constructed statutory scheme, there is no judicial power to exclude relevant evidence unless admission of that evidence would violate the Constitution or a specific statutory or Rules provision.[52] If in

---

[51] It should be noted that in this instance the exceptions lead to *admission* of evidence, rather than its exclusion, and thus are not in tension with the general preference for admissibility declared in Rule 402. *See* note 49, *supra*.

[52] Indeed, so explicit is the language of Rule 402 that on several occasions the United States has urged this Court — although the Court has not passed on the issue — that Rule 402 not only eliminated common-law rules of evidence, but also "stripped the federal judiciary of its supervisory powers to exclude evidence obtained through gross misconduct by agents of the United States," where that misconduct does not violate the Constitution or a statute. *United States v. Payner*, 447 U.S. 727, 751 n.17 (1980) (Marshall, J., dissenting). The Court in *Payner* held that "the supervisory power does not authorize a federal court to suppress otherwise admissible evidence on the ground that it was seized unlawfully from a third party not before the court"; therefore there was no need to address any conflict between continued use of the supervisory power to exclude evidence and Rule 402. *See also United States v. Caceres*, 440 U.S. 741, 755 & n.22 (1979) (declining to adopt a rule under the supervisory power that would require exclusion of evidence obtained from electronic eavesdropping solely because it violated agency regulations, "without pausing to evaluate the Government's challenge to our power to do

Bourjaily the text of the Rules superseded a common-law doctrine that had been explicitly announced *by this Court* (see pp. 21-22, *supra*), *a fortiori* Rule 402 means that the *Frye* doctrine, which had enjoyed only a mixed reception in the lower federal courts, cannot stand after 1975 as an independent judge-made rule of exclusion.

2. Legislative History

As this Court held in *Bourjaily*, "[i]t would be extraordinary to require legislative history to *confirm* the plain meaning of" a Federal Rule of Evidence. 483 U.S. at 178 (emphasis in original). But even if consulted, the legislative history confirms that Congress meant what it plainly said in Rule 402.

Rule 402 was the key to Congress's goal of creating a coherent, self-contained set of rules ensuring uniformity in federal evidence law. The Senate Report accompanying the bill that became the Federal Rules of Evidence cited the need for "a comprehensive code of evidence . . . to govern the admissibility of proof in all trials before the Federal courts because of the lack of uniformity and clarity in the present law of evidence on the Federal level." S. Rep. No 93-1277, 93rd Cong., 2d Sess. (1974), at [1974] U.S. Code

---

so"). *See also* Sara Sun Beale, *Reconsidering Supervisory Power in Criminal Cases: Constitutional and Statutory Limits on the Authority of the Federal Courts*, 84 Colum. L. Rev. 1433, 1488-89 & n.324 (1980) (noting that the Court heard argument twice, but did not decide, a case reviewing a Second Circuit ruling rejecting the Government's reading of Rule 402, *United States v. Jacobs*, 547 F.2d 772, 777 (2d Cir. 1976), *cert. dismissed as improvidently granted*, 436 U.S. 31 (1978)). Judge Bork has expressed the view that Rule 402 *does* preclude exercise of judicial supervisory power except "when specific constitutional or legal provisions call for that remedy." *United States v. Mount*, 757 F.2d 1315, 1322-24 & n.7 (1985) (Bork, J., concurring).

This Court need not, of course, resolve the issue of survival of the Judiciary's supervisory power in this area in order to conclude that Congress plainly meant in Rule 402 to leave no room for judicial application of traditional common-law rules of evidence that were not incorporated into the Rules. Thus, in *Jacobs*, the Second Circuit declined to find that Rule 402 impinged upon the Judiciary's supervisory power, while at the same time recognizing that "[t]he obvious purpose of [Rule 402] was to bar common law rules of evidence or state rules of evidence, if inconsistent" with the Rules. 547 F.2d at 777.

Cong. & Ad. News 7054. Rule 402 is "'the keystone to the whole scheme,'" designed both "to sweep away all pre-existing rules of exclusion" and to "mak[e] clear that the rest of the Evidence Rules are exceptions to the basic rule of relevance." 22 Wright & Graham, *Federal Practice and Procedure: Evidence* § 5192 (1978), at 177 (1978) (hereinafter "Wright & Graham").

Inclusion of a statutory provision that would "wipe the slate clean" had been understood since 1872 to be an obviously essential element of *any* attempt to truly codify evidence law. *See id.* at 178-79 & n.9. *See also* Advisory Committee's Note to Rule 402, ¶ 1 ("The provisions that all relevant evidence is admissible, with certain exceptions, and that evidence which is not relevant is not admissible are 'a presupposition involved in the very conception of a rational system of evidence.' Thayer, *Preliminary Treatise of Evidence* 264 (1898). They constitute the foundation upon which the structure of admission and exclusion rests"). Rule 402 is that provision.

There are clear indications that both the drafters of Rule 402 and the legislators who approved it were aware of the intended effect of Rule 402. The Advisory Committee's Note to Rule 402 is particularly instructive here, given that Congress found Rule 402 "noncontroversial" and did not amend it in any significant way. *See* 22 Wright & Graham, § 5191, at 173-74. Enumerating the sources for exclusionary rules authorized in Rule 402, ¶ 3 of the Note explains that exclusion "may be called for by these rules, by the Rules of Civil and Criminal Procedure, by Bankruptcy Rules, by Act of Congress, or by constitutional considerations." The omission of any reference to *common-law rules* in ¶ 3 cannot be deemed inadvertent, for ¶ 5 specifically refers to "the scope of the common law rules" in addressing a different subject; the drafters were aware of the disjunction between the sources listed in Rule 402 and the common-law rules of evidence.[53] Finally, apart from the Advisory

---

[53] Further striking evidence of the Committee's plain intent lies in ¶ 1 of the Note to Rule 402, which indicates that Rule 402 is "similar" to § 351 of the California Evidence Code — a provision that had been adopted for the purpose of "preclud[ing] the possibility that valid restrictions on the admissibility of evidence in addition to those declared by statute will remain.'" 22 Wright & Graham, § 5192, at 179 n.10 (quoting legislative history of Uniform Rule of Evidence 7, which became California Evidence Code § 351).

Committee's Note which was before Congress when it enacted the Rules, congressional hearings put Congress on notice that the plain effect of Rule 402 was to do away with judicially created exclusionary rules.[54]

B. The *Frye* Rule Is Not Contained in or Authorized by the Federal Rules of Evidence

Petitioners have shown that the *Frye* rule cannot stand *independent* of the Federal Rules of Evidence. We now turn to the question whether the *Frye* rule can be found *in* the Federal Rules themselves. The analysis in Part I-A frames the proper approach to answering that question. As we have seen, Congress "wiped the slate clean" by the broad declaration of admissibility in Rule 402, and then inserted specific provisions to preserve those common-law rules of exclusion that it wished to retain.

As a reading of the Federal Rules of Evidence will make plain, there is nothing in the text, anywhere, that remotely resembles the *Frye* rule. Article VII of the Rules deals extensively with the topic "Opinions and Expert Testimony" (containing six discrete provisions dealing with such testimony, in Rules 701 through 706), but the proposition that scientific testimony should not be received unless "generally accepted" is nowhere to be found. The omission is striking, for the *Frye* rule was notorious at the time the Rules were adopted. *See* p. 17, *supra*; *see also* note 57, *infra*. Had the drafters intended to preserve *Frye*, their method makes clear that

---

This borrowing is hardly surprising. One of the members of the Advisory Committee had been a drafter of the California code, and to a large extent the Advisory Committee "used the California Evidence Code as a model." *Id.* §§ 5191, at 175; 5199, at 222 & n.16.

[54] After reviewing the legislative record, Professors Wright and Graham reported: "Virtually all of the witnesses in congressional hearings assumed that the effect of adoption of the Federal Rules of Evidence would be to foreclose courts from changing rules of evidence by decision," and "[t]he record strongly suggests that Congress assumed that, except where the Evidence Rules otherwise provide, there would be no decisional law of evidence." 22 Wright & Graham, § 5199, at 222 & n.17.

they would have included it in the text.[55] The omission is not surprising, however, for the Advisory Committee's Notes manifest an intention to broaden the admissibility of expert testimony and to ensure that it would be free of obstacles that had been erected by prior law.[56] This Court has noted the "liberal thrust of the Federal Rules," and in particular how Rules 702 through 705 follow a "general approach of relaxing the traditional barriers to 'opinion' testimony." *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988).[57]

The common-law *Frye* rule operated as a categorical, *per se* bar to admitting scientific evidence that lacked "general acceptance,"

---

[55] Indeed, the *Frye* rule is not even mentioned in the Advisory Committee's Notes or the legislative deliberations.

[56] See Advisory Committee's Notes to Rule 702 (expanding expert testimony beyond responses to hypothetical questions; rule is "broadly phrased" to permit admissibility); Rule 703 (overturning the hearsay obstacle to admissibility of expert opinion to "broaden the basis for expert opinions"); Rule 704 (eliminating the objection to admissibility of expert opinion on the "ultimate issue" in the case, thereby facilitating the "basic approach" of the rules to admit expert testimony whenever "helpful to the trier of fact"); Rule 705 (eliminating the "complex and time consuming" hypothetical question rule).

[57] This point has been echoed by leading commentators. As Professor Berger has written, "Wigmore, McCormick, and other eminent commentators . . . complained for decades about common-law restrictions on opinion evidence that deprived triers of fact of valuable information needed for sounder adjudications." Margaret Berger, *United States v. Scop. The Common Law Approach to an Expert's Opinion About a Witness's Credibility Still Does Not Work*, 55 Brooklyn L. Rev. 559, 559 (1989). "As technology advanced and expert testimony became more important in the resolution of increasingly complex litigation, unnecessary impediments became unacceptable," and in particular, "it became clear that the *Frye* rule might block the introduction of important and useful testimony." Judge Jack B. Weinstein, *Improving Expert Testimony*, 20 U. Rich. L. Rev. 473, 476-77 (1986). "[T]the rules reflect an enlightened, academic view of opinion testimony that dates back some fifty years." Judge George C. Pratt, *A Judicial Perspective on Opinion Evidence Under the Federal Rules*, 39 Wash. & Lee L. Rev. 313, 314 & n.5 (1982) (citing authorities). The statutory scheme "rel[ies] heavily on the adversary system," and trusts the ability of counsel to present such testimony and of juries to evaluate it. *Id.* at 313. The goal "[t]hat evidence scholars had long been seeking ha[s] now come to pass." Weinstein, *supra*, at 477.

without further inquiry into the validity of the scientific technique or the possible value of the evidence in a particular case. To find *Frye* preserved in the Rules, then, one would look for a categorical rule of exclusion targeting such evidence, "novel" or otherwise. It is not there. There is only one *per se* exclusionary rule respecting expert opinion evidence, Rule 704(b), and it deals with an entirely different subject, forbidding ultimate expert opinions on the sanity of a criminal defendant. Note, 72 Cornell L. Rev. 620 (1987). No other subject-matter exclusion of expert testimony appears elsewhere in Article VII of the Rules. Nor can any special barrier to scientific evidence be found in the lengthy list of categorical, *per se* grounds for excluding evidence found under Article IV of the Rules, entitled "Relevancy and Its Limits." *See* p. 22, note 47, *supra*.

Despite the lack of an explicit provision excluding testimony about scientific theories that lack general acceptance, some proponents of the *Frye* rule contend that *Frye* has survived, albeit in different words, in Rule 702 or Rule 703.

Rule 702

A plain reading of Rule 702 provides no support for proponents of *Frye*. Rule 702 states:

> **Rule 702. Testimony by Experts**
>
> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

As is apparent from the text of the Rule and the accompanying Advisory Committee's Note, the trial court, when presented with a proffer of expert testimony, must answer two questions:

First, is this a situation in which "specialized knowledge will assist the trier of fact?" In the words of the Advisory Committee's Note to Rule 702, the question is "[w]hether the situation is a proper one for the use of expert testimony," an inquiry that turns on whether "the untrained layman would be qualified to determine intelligently and to the best possible degree the particular issue

without enlightenment from [experts]."[58]

Second, if the jury would benefit from expert testimony, the trial court must then determine whether the witness is "qualified as an expert" in that specialized field. If so, that expert "may testify thereto," that is, concerning specialized knowledge within that field that is pertinent to the issues in dispute.

The argument for finding *Frye* in the words of Rule 702 is that scientific opinion evidence lacking general acceptance should be regarded as testimony that cannot "assist the trier of fact to . . . determine a fact in issue."[59] But this misreads Rule 702. Nothing

---

[58] The Advisory Committee's Note repeatedly focuses on the issue of whether "specialized knowledge," as opposed to common knowledge, would benefit the trier of fact. It begins: "An intelligent evaluation of facts is often difficult or impossible without the application of some scientific, technical, or other specialized knowledge." *Id.* ¶ 1. In explaining how a judge is to determine "[w]hether the situation is a proper one for the use of expert testimony," the Advisory Committee Note explains: "There is no more certain test for determining when experts may be used than the common sense inquiry whether the untrained laymen would be qualified to determine intelligently and to the best possible degree the particular issue without enlightenment from those having a specialized understanding of the subject involved in the dispute." *Id.* ¶ 3 (quoting Ladd, *Expert Testimony*, 5 Vand. L. Rev. 414, 418 (1952)).

This explanation is highly instructive. As a key canon for interpreting the Rules, this Court has noted that where "Congress did not amend the Advisory Committee's draft in any way that touches on the question before us, the Committee's commentary is particularly relevant in determining the meaning of the document Congress enacted." *Beech Aircraft*, 488 U.S. at 165 n. 9. Where there is any ambiguity as to "[w]hat was on the Committee's mind," the Court has closely examined the sources cited by the Committee. *Id.* at 165.

[59] *See, e.g., United States v. Christophe*, 833 F.2d 1296, 1299 (9th Cir. 1987) (holding Rule 702 embodies requirement of "appreciable help," which is not met "[u]nless the testimony conforms to a generally accepted explanatory theory," necessary to achieve "the best available approximation of truth in the judgment of the majority of scientists who work in the particular specialty involved"); *United States v. Kozminski*, 821 F.2d 1186, 1194 (6th Cir. 1987), *aff'd in part on other grounds and remanded in part*, 487 U.S. 931 (1988) (setting out "a four-part test" under Rule 702 that goes beyond the "qualified expert" and "proper subject" tests found in the rule, to insist on "conformity to a generally accepted explanatory theory" whose value "outweighs any prejudicial effect"); *United States v. Two Bulls*, 918 F.2d 56, 60 (8th Cir. 1990), *reh'g granted, vacated*, 925 F.2d 1127 (8th Cir. 1991) (*en banc*) (without any statutory analysis, holding that "we feel Rule 702 and *Frye* both require the same general approach to the admissibility of new scientific

in the language of Rule 702 invites the trial court to bar an expert from the stand based on the judge's impression of the value of the expert's opinion. Rule 702 authorizes only a generic inquiry whether "specialized knowledge will assist the trier of fact," and a further inquiry whether the particular witness is "qualified" based on "knowledge, skill, experience, training *or* education" (emphasis added).[60] The function of Rule 702 is to make clear that *if* these requirements are met, the witness may testify "as an expert."[61]

Indeed, the structure of Rule 702 makes clear that the judge can answer these questions *without even knowing what opinion the expert will offer upon assuming the stand* and, thus, without knowing whether the expert's opinion is in the mainstream or on the fringe. For once it is determined that "the situation is a proper one for the use of expert testimony" because "scientific, technical or other specialized knowledge" will assist the trier of fact (*see* p. 30, *supra*) and that the proffered expert is qualified on the subject, then, in the words of Rule 702, the expert "may testify thereto in the form of an opinion or otherwise."[62]

---

evidence," in barring "speculative and conjectural testing").

[60] The Advisory Committee Note to Rule 702, ¶ 4, explains that the Rule's definition of a "qualified" expert was intentionally made broad: "the expert is viewed, not in a narrow sense, but as a person qualified [in one of these five ways]." None of these five criteria remotely suggests that only experts holding "generally accepted" views are qualified, and indeed Merrell has regularly conceded in Bendectin trials that plaintiffs' witnesses are qualified within the meaning of Rule 702.

[61] Three other Rules then come into play to permit the trier to benefit from that expert's knowledge: Rules 704 and 705 lift the opinion ban of Rule 701, permitting the witness to testify to the ultimate issue in the case, without a rigid format for disclosing of the underlying facts or data; and Rule 703 lifts the requirement, found in Rules 602 and 701, that a witness testify only from personal knowledge of the facts in the case.

[62] Two other considerations confirm that the reading the proponents of *Frye* attempt to give Rule 702 is misplaced. First, Rule 702 treats equally, and without any distinction, "scientific, technical or other specialized knowledge." But the *Frye* rule by its terms is applicable only to scientific evidence. If the framers had intended to incorporate *Frye* via Rule 702, it is inconceivable that they would have done so without a single linguistic trace of that intention either in the text or the Advisory Committee's Notes. Second, even on the hypothesis that Rule 702 were misinterpreted as authorizing a judge to evaluate the helpfulness of the witness' *particular* opinion, it is preposterous to think

Courts that have carefully analyzed the "specialized knowledge" standard and the Advisory Committee's Note to Rule 702 have held that expert testimony satisfies Rule 702 whenever the issue at stake is not easily ascertainable through the application of common knowledge, and the witness at hand possesses specialized knowledge bearing on that issue.[63]

On the issue of causation in a toxic tort case, common sense dictates that the jury is incapable of making a decision without the benefit of expert testimony, and that the "assist" requirement of Rule 702 has been met. *See, e.g., Christophersen v. Allied Signal Corp.*, 939 F.2d 1106, 1116 (5th Cir.) (Clark, C.J., concurring in the judgment), *cert. denied*, 112 S. Ct. 1280 (1991) (case alleging that worker's occupational exposure to nickel and cadmium triggered colon cancer; "[o]bviously, a medical opinion as to

---

that only "generally accepted" views will be helpful to the trier of fact. Science is a field of constant discovery and advance in reasoning, and breakthroughs inevitably take time to gain general acceptance. It is simply not plausible that the drafters would have used the words in Rule 702 (even as misinterpreted by the proponents of *Frye*) if the intention had been to carry forward the *Frye* ban on evidence lacking general acceptance.

[63] *See, e.g., Douglass v. Hustler Magazine, Inc.*, 769 F.2d 1128, 1142 (7th Cir. 1985), *cert. denied*, 475 U.S. 1094 (1986) ("Rule 702 of the Federal Rules of Evidence defines the scope of permissible expert testimony very broadly. The rule and accompanying Advisory Committee Note indicate that such testimony is admissible whenever it concerns a *topic* on which a lay jury would be assisted by such testimony") (emphasis added); *United States v. Onumonu*, 967 F.2d 782, 787 (2d Cir. 1992) (holding under Rule 702 that expert testimony "would have assisted the jury in resolving the only contested issue in the case," because it was "likely that the average New York juror knows little about" subject); *Busby v. City of Orlando*, 931 F.2d 764, 784 (11th Cir. 1991) (overturning district court's exclusion of expert statistical summary because "even the most competent jury could not have" fully understood complex statistics by simple "examination of the original documents," thus finding "assistance to the trier of fact" standard met); *United States v. Rivera Rodriguez*, 808 F.2d 886, 888 (1st Cir. 1986) (quoting Advisory Committee's Note and finding Rule 702 met because it was "doubtful that the jurors could have determined, without the aid of the expert witness," the issue at hand, which was not "within the common knowledge of the juror"; "an appropriate explanation by an expert is preferable to jury speculation"); *Wilder Enterprises v. Allied Artists Pictures*, 632 F.2d 1135, 1143 (4th Cir. 1980) (Rule 702 met because "testimony would help the jury understand the intricacies of film distribution and the nature and effects of splits, subjects which are not common knowledge").

causation would assist the trier of fact in this highly technical scientific case"). The only remaining, necessary determination under Rule 702 is whether the proffered expert is "qualified by knowledge, skill, experience, training, or education" to provide an opinion on that subject. *Frye*'s requirement that the expert's views be "generally accepted" is nowhere in Rule 702.

Indeed, precisely because *Frye* is *not* in Rule 702, those who would like to see district courts have greater control over the admissibility of expert testimony have proposed revisions to Rule 702 to provide it. But, as these efforts to secure revision reflect, the means for securing change from the present Rules' receptivity to expert testimony must be those prescribed in the Rules Enabling Act, not a tortured effort to find *Frye* in the interstices of rules that plainly do not embrace it.[64]

Rule 703

Nor can *Frye* be "found" in Rule 703. Rule 703 provides:

> **Rule 703. Bases of Opinion Testimony**
>
> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

The argument advanced by *Frye* proponents is that the phrase "reasonably relied upon by experts in the particular field in forming opinions" in the second sentence of the rule incorporates the *Frye* rule. This represents a double misreading of Rule 703.

---

[64] Moreover, even if the proponents of such a rules change were correct that such a change would be desirable, it would be extremely controversial to make the change applicable to state law diversity actions. As we explain in Part I-C, *infra*, barring expert testimony on the basis of *Frye* can have an enormous substantive effect on state law claims. *See, e.g.*, Judge Jack B. Weinstein, *Rule 702 of the Federal Rules of Evidence is Sound; It Should Not Be Amended*, 138 F.R.D. 631, 636 (1991). Historically, the Rules drafters have shied away from imposing outcome-determinative evidentiary rules upon state law claims, explicitly exempting state law claims from those evidentiary rules that might have that substantive effect. *See* Part I-C, *infra*.

To begin with, Rule 703 provides no textual support for placing special limitations on expert testimony; quite the contrary, its function is to remove burdens imposed by other rules. It does *not* say that experts' opinions, to be admissible, must be affirmatively based on facts and data "reasonably relied upon by experts in the particular field . . . ." It says only that *if* the facts and data are of that character, they "need not be admissible in evidence." Consistent with Rule 703, an expert could rely upon non-hearsay data (for example, symptoms observed during his own physical evaluation of a patient) to formulate an opinion, and that opinion would be admissible whether or not a consensus of the scientific community would rely upon those symptoms to derive an opinion. The expert may do so because the first sentence of Rule 703 explicitly permits an expert to rely, like any *other* witness, on "facts or data . . . perceived by" him or her.

The argument that *Frye* is in Rule 703 also totally misconstrues the second sentence of that rule. The purpose of that sentence, as its literal meaning conveys, is to free experts to testify without having to admit into evidence the data they rely upon for reaching their conclusions.

Rule 703 concerns the "bases" for expert testimony. As the Advisory Committee's Note to Rule 703 indicates, under the common law, an expert could base his opinion on either (1) personal knowledge or (2) assumed facts supported by evidence *in the record*, typically in the form of a hypothetical question. The first sentence of Rule 703 merely preserves this practice, as the Note indicates in ¶ 1. The innovation of the second sentence of Rule 703 is to add a third basis for expert opinion: information learned by an expert outside of the trial, provided that such information is "of a type reasonably relied upon by experts in the particular field." For example, scientists can now predicate an opinion, as Merrell's Dr. Lamm did in his affidavit submitted by Merrell in support of its summary judgment motion, upon "data on birth defects" gathered by others throughout the world. (J.A. 33).

Thus, the purpose of Rule 703 was to expand the "bases" of expert testimony, not to limit the subject matter of the expert testimony. Rule 702 governs the subject matter issue, permitting an expert to convey "specialized knowledge" from a given field; Rule 703 then permits the expert to rely on non-record facts or data — what would otherwise be hearsay — "[i]f of a type reasonably relied

upon by experts in the particular field in forming opinions or inferences upon the subject."

The function of this second sentence has nothing to do with scrutinizing the particular opinions offered by an expert; its sole mission is to remove the requirement of Rule 602 that a witness generally must have "personal knowledge" of the matter he is addressing. The language of Rule 602 confirms this reading of Rule 703. Rule 602 states that its requirement "is subject to the provisions of Rule 703, relating to opinion testimony by expert witnesses." The Advisory Committee's Note to Rule 602, ¶ 3, explains that despite Rule 602, when an expert testifies to specialized knowledge, Rule 703 allows the expert "to express opinions based on facts of which he does not have personal knowledge." Thus this second sentence streamlines the trial process by permitting experts to refer to what colleagues told them about a case, without a need to bring in the witnesses having personal knowledge, thus cutting down on the number of experts needed to provide comprehensive information to a jury.[65]

---

[65] The legislative history of Rule 703 confirms its plain language and this characterization, demonstrating that it was designed to permit experts to refer freely to the types of hearsay information routinely referred to in their fields, thus streamlining the trial process, in a manner akin to the "business records exception" to the hearsay rules. The Advisory Committee's Note states that "the rule is designed to broaden the basis for expert opinions beyond that current in many jurisdictions and to bring the judicial practice into line with *the practice of the experts themselves when not in court*." (Emphasis added). Using the example of a diagnosing physician, the Note states that many sources relied upon by experts "are admissible in evidence, but only with the expenditure of substantial time in producing and examining various authenticating witnesses," and concluded that the expert's "validation [of these sources], expertly performed and subject to cross-examination, ought to suffice for judicial purposes."

The lower federal courts have had no difficulty discerning the function of the second sentence of Rule 703. *See, e.g.*, *Ambrosini* v. *Labarraque*, 966 F.2d 1464, 1466 (D.C. Cir. 1992); *DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 953 (3d Cir. 1990); *United States* v. *Unruh*, 855 F.2d 1363, 1376 (9th Cir. 1988), *cert. denied sub nom. Forde* v. *United States*, 488 U.S. 974 (1988); *United States* v. *Kail*, 804 F.2d 441, 447 (8th Cir. 1986); *United States* v. *Wright*, 783 F.2d 1091, 1100 (D.C. Cir. 1986); *First National Bank of Kenosha* v. *United States*, 763 F.2d 891, 895 (7th Cir. 1985); *Mannino* v. *International Manufacturing Co.*, 650 F.2d 846, 851 (6th Cir. 1981).

Moreover, even if the words of Rule 703 *could* be construed as a limit upon the admissibility of expert opinions generally, they do not constitute an adoption of the *Frye* rule. Here, plaintiffs' experts consulted the very facts and data that scientists generally rely upon in formulating an opinion about toxic causation (see p. 4-6, *supra*). What Merrell protests is not the experts' choice of data base, but the conclusions they drew from their analysis of that data. By its terms, Rule 703 has nothing to do with the controversial nature of the expert's conclusion. Rule 703 is a limitation upon the type of *data* to which the expert *applies* his or her thinking process, not a restriction upon the conclusions the expert reaches from that process.[66]

The framers of the Rules in their present form were not oblivious to the danger that there might be scientists or other experts who, for a fee, would testify to highly dubious opinions. The very first words of the Advisory Committee's Note to Rule 706 refer to "[t]he practice of shopping for experts [and] the venality of some experts." The framers' solution, however, was not to exclude controversial testimony *per se*, but to arm the opposition and the district court with procedural tools to strengthen the adversary process and thus to ensure that the trier of fact would receive an accurate picture respecting the state of scientific opinion. Although Rule 705 permits experts to testify without first offering the facts or data to the trier of fact, the Advisory Committee's Note to Rule 705 points to recent changes in discovery procedures designed to ensure advance disclosure of the expert's views to facilitate effective cross-examination.[67] In Rule 803(18), the framers significantly expanded the "learned treatise" exception to the hearsay rule to better enable

---

[66] Where the complaint is that an expert is deriving a conclusion from a *data base* that is not generally accepted as reliable, e.g., determining causation from the alignment of the planets, and where the data base is one that is not itself admissible, it is plausible to argue that the data base is one not "reasonably relied upon by experts in the particular field in forming opinions" and thus that testimony as to the opinion is barred by hearsay. But this is a far cry indeed from the Ninth Circuit's use of *Frye* to bar to the admissibility of opinions that *are* derived from the generally accepted data base but that supposedly constitute conclusions that are not "generally accepted."

[67] Fed. R. Civ. P. 26(b)(4). *See, e.g.*, Weinstein, *supra* note 57, at 483-85; Pratt, *supra* note 57, at 322-25.

a cross-examiner to show the trier of fact where an expert departs from the mainstream. *See* Lynne Heckert, "Use of Learned Treatises at Trial," 1984 Trial Lawyer's Guide 165.

Moreover, in Rule 706(a) Congress showed the ultimate choice it made regarding the policy concern that the evidence rules might permit marginal testimony based on extreme positions. Congress addressed that concern *not* by enacting an indiscriminate *Frye*-type categorical rule excluding scientific testimony lacking general acceptance, but rather by empowering district courts to appoint experts of their own choosing to testify as neutral witnesses. The Advisory Committee's Note shows that this power was conferred to deal with the problem of the expert as "hired gun":

> The practice of shopping for experts, the venality of some experts, and the reluctance of many reputable experts to involve themselves in litigation, have been matters of deep concern. Though the contention is made that court appointed experts acquire an aura of infallibility to which they are not entitled, . . . the trend is increasingly to provide for their use. While experience indicates that actual appointment is a relatively infrequent occurrence, the assumption may be made that the availability of the procedure in itself decreases the need for resorting to it. The ever-present possibility that the judge *may* appoint an expert in a given case must inevitably exert a sobering effect on the expert witness of a party and upon the person utilizing his services.

(Emphasis added). There are, of course, some who contend that this arsenal is inadequate. But, as already noted, Rule 402 identifies the means by which additional *per se* rules can be promulgated, and judge-made rules like *Frye* are not among them. *See* pp. 23-26, *supra*.

Finally, it should be noted that Rule 403 empowers district judges to engage in *ad hoc*, case-specific balancing to exclude otherwise admissible evidence (including expert testimony) "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury . . . ." Application of this test in particular cases may result in the exclusion of evidence that the *Frye* rule was designed to block. However, the *per se* quality of the *Frye* rule pretermits this weighing process and removes the discretion from the trial judge without according the testimony the presumption of admissibility

that must be "substantially outweighed" by the particulars of the case."[68]

In sum, the Rules reflect broad hospitability to the receipt of expert testimony, and a reliance upon the ultimate safeguard that this Court identified in *Barefoot v. Estelle*, 463 U.S. 880, 898 (1983):

> [T]he rules of evidence generally extant at the federal . . . level[] anticipate that relevant, unprivileged evidence should be admitted and its weight left to the fact-finder, who would have the benefit of cross examination and contrary evidence by the opposing party.

---

[68] In the instant case, for example, the following factors would have to be considered before the plaintiffs' expert testimony could be excluded by a trial court under Rule 403:

(1) To exclude the testimony in this case non-suits the plaintiffs, as it is impossible to prove causation in a toxic tort cause except through expert testimony; thus the prejudice to the plaintiffs is absolute. The usual occasion for invoking Rule 403 is to exclude expert testimony that might confuse the jury, and to allow the jury to rely upon its own common sense instead; that course visits no similar injury upon the party whose expert evidence is excluded.

(2) This is not a case where the evidence is likely to confuse the jury: it is not a case where the jury is to be dazzled by a machine that it cannot understand, but rather one where the jury will know that plaintiffs' experts have drawn conclusions from the traditional data base that conflicts with the conclusions of many other experts who have looked at the same database. *See* pp. 43-44, note 71, *infra*. The testimony here is no more beyond the jury's understanding than is *any* medical evidence in any case.

(3) Neither is this a case where the nature of the disagreement is beyond a jury's comprehension; the debate between the experts described *supra* at pp. 8-12, is quite straightforward.

(4) On its face, the proffered testimony of plaintiffs' witnesses has substantial probative value. Indeed, as the Statement shows, their position on both areas of disagreement with Merrell's experts is both intrinsically substantial and has significant support in the scientific community.

(5) Finally, the district court could exclude this otherwise relevant evidence only upon a finding that its probative value was "substantially outweighed" by its potential to mislead or confuse the jury. As the Third Circuit has opined in another Bendectin case, "Rule 403 is an unlikely basis for exclusion." *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 957 (3d Cir. 1990). *See also Busby v. City of Orlando*, *supra* note 63, 931 F.2d at 784.

In *Barefoot*, which involved the admissibility of psychiatrists' opinions that were challenged by the American Psychiatric Association as heretical,[69] this Court stressed that "the purpose of the jury is to sort out the true testimony from the false, the important matters from the unimportant matters, and, when called upon to do so, to give greater credence to one party's expert witnesses than another's. Such matters occur routinely in the American judicial system, both civil and criminal." *Id.* at 902 (1983) (internal quotation omitted). The Court repeated that emphasis in *Beech Aircraft*, *supra*, noting "the liberal thrust of the Federal Rules" with regard to opinion testimony. 488 U.S. at 169, again affirming that "the ultimate safeguard" in the Federal Rules is "the opponent's right to present evidence tending to contradict or diminish the weight of those conclusions." 488 U.S. at 168.

---

[69] *Barefoot* involved a constitutional challenge to the receipt of psychiatric testimony on future dangerousness in a state criminal proceeding. The mainstream of the psychiatric profession believed that psychiatrists' efforts to make such predictions are totally unreliable, a point brought to the Court's attention in an amicus curiae brief of the American Psychiatric Association. Without challenging the accuracy of the APA's headcount, the Court responded:

> If [the four psychiatrists whose testimony was at issue] are so obviously wrong and should be discredited, there should be no insuperable problem in doing so by calling members of the Association [to testify against them.] . . . We are unconvinced, however, at least as of now, that the adversary process cannot be trusted to sort out the reliable from the unreliable evidence . . . .
>
> ***
>
> All of these doubts about the usefulness of psychiatric predictions can be called to the attention of the jury . . . Petitioner's . . . argument . . . is founded on the premise that the jury will not able to separate the wheat from the chaff. We do not share in this low evaluation of the adversary process.

463 U.S. at 900-01 & n.8.

C. The *Frye* Rule Would Often Be Outcome-Determinative in State-Law Diversity Actions. This Precludes Its Application to Diversity Actions As an Independent Judge-Made Rule, And Confirms That Congress Did Not Intend to Incorporate It *Into* the Federal Rules of Evidence

Our demonstration to this point has not taken account of the federalism concerns that flow from the fact that the Federal Rules of Evidence apply to diversity actions governed by state substantive law. Those concerns strongly reinforce the conclusion that *Frye* has not survived the enactment of the Federal Rules, either as an independent judge-made rule or as assimilated into the Rules.

The Federal Rules of Evidence as enacted in 1975 were crafted so as not to alter the substantive law applicable in diversity cases. Early in the drafting process Judge Weinstein warned of the "residual federalism issues" posed by certain categories of rules: burdens of proof, presumptions and rules concerning the competency of witnesses. *See* Weinstein, *The Uniformity-Conformity Dilemma Facing Draftsmen of Federal Rules of Evidence*, 69 Colum. L. Rev. 353, 361, 363-70 (1969). When such concerns were not fully heeded in the original version of the Rules, Congress held up promulgation and engaged in a review and amendment process, largely out of concern about the threat to state interests posed by the Rules. "[T]he Rules were criticized for failing to provide recognition in diversity cases for state rules of evidence that might be thought of as substantive under the *Erie* doctrine," and Congress made specific amendments to the original version of the Rules to decree "an adherence to state law in diversity cases on issues of presumptions [Rule 302], privileges [Rule 501], and competency of witnesses [Rule 601] that many commentators felt was required by the *Erie* case anyway." 22 Wright & Graham, § 5006, at 106, 108. Out of its concern that "state rules that ought to have been considered 'substantive' were overridden in the Court's version," Congress "sought to assure a minimum of tampering with state substantive rights," thus policing "the limitation specified in the second sentence of the 1934 Rules Enabling Act against abridging substantive rights." Olin Guy

Wellborn III, *The Federal Rules of Evidence and the Application of State Law in the Federal Courts*, 55 Tex. L. Rev. 371, 401 (1977).

Given this history, it is inconceivable that Congress meant either to incorporate the *Frye* rule or to leave it intact. Whether *Frye* is conceived to be a common-law doctrine functioning independent of the Rules, or as a test that might plausibly be read into some provision of the Rules, the *Frye* rule applied by the court below inescapably will alter the substantive outcome of state law cases depending upon whether they are tried in federal or state court.

This point can be made most concretely by consideration of the District of Columbia Court of Appeals' decision in *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C. 1986), *cert. denied*, 110 S. Ct. 1121 (1990). There, as here, Merrell argued that plaintiffs could not prove that Bendectin causes limb reductions. On a record substantially similar to that which plaintiffs have proffered here, the D.C. Court of Appeals upheld a jury finding that plaintiffs had met their burden of proving causation. Rejecting Merrell's argument that causation could be established only through an epidemiological study whose results meet the 95 percent confidence level, that court held that causation could be established by the combined effect of analysis of chemical structure, in vivo and in vitro studies, and epidemiological results falling short of the 95 percent confidence level. Whatever the probative effect of any one of those factors standing alone, they "combined to produce a whole that was greater than its parts." 506 A.2d at 110.[70]

If *Frye* is applicable, the next suit brought in the District of Columbia could be removed by Merrell to federal court, and evidence that the D.C. Court of Appeals held sufficient to prove plaintiff's case *would be inadmissible*. It is difficult to conceive a rule that was more outcome-determinative, that would more surely induce forum-shopping, that would more plainly frustrate state or

[70] The *Oxendine* court's reasoning paralleled this Court's in *Bourjaily*, *supra*, 483 U.S. at 179-80 (it is a "simple fact of evidence life" that "individual pieces of evidence, insufficient in themselves to prove a point, may in cumulation prove it. The sum of an evidentiary presentation may be greater than its constituent parts").

local policy governing the bases of substantive tort liability, and that would more lead to unequal administration of the laws (for only those victims who share citizenship with Merrell could have hope of securing the benefits of state law declaring their proof sufficient). In every relevant respect, the rule would be "substantive" within the meaning of *Erie* and its progeny.

It is petitioners' position that, under California law — as under D.C. law — the evidence petitioners have proffered would permit a recovery for petitioners. Clearly, this evidence would be admissible under California law.[71] And while there is no case in

[71] California is one of the states that adopted the *Frye* rule, *see People v. Kelly*, 549 P.2d 1240, 1244 (Cal. Supreme Ct. 1976), but its use has been limited solely to the original context of *Frye — criminal* cases — and California has not followed the Fifth and Ninth Circuits in applying *Frye* to civil cases. Moreover, California has held that a "general acceptance standard may be applied *only* to "the thing from which the deduction is made." *Frye*, 293 F. at 1014. That is, in California criminal cases the *Frye* rule applies only when "the evidence is produced by a machine" or other compelling, non-subjective means, on the theory that "like many laypersons, jurors tend to ascribe an inordinately high degree of certainty to proof derived from an apparently 'scientific' mechanism, instrument or procedure." *People v. McDonald*, 690 P.2d 709, 724 (Cal. Supreme Ct. 1984). *McDonald* therefore held unanimously that *Frye* cannot be used to exclude the conclusions of experts who have studied available data on a particular subject and give their own informed assessment of the data, because such testimony does not raise the concerns addressed by *Frye*. *Ibid.*

The *McDonald* court explained: "When a witness gives his personal opinion on the stand — even if he qualifies as an expert — the jurors may temper their acceptance of his testimony with a healthy skepticism born of their knowledge that all human beings are fallible," and noted that "[w]e have never applied the *Kelly-Frye* rule to expert medical testimony, even when the witness is a psychiatrist and the subject matter is as esoteric as the reconstitution of a past state of mind or the prediction of future dangerousness, or even the diagnosis of an unusual form of mental illness not listed in the diagnostic manual of the American Psychiatric Association *Id.* at 724 (citations omitted). In *People v. Stoll*, 783 P.2d 698, 710-11 (Cal. Supreme Ct. 1989), the California Supreme Court reaffirmed this reasoning and explained that for *Frye* to apply there must be "an unproven technique or procedure [that] appears both in name and description to provide some definitive truth which the expert need only accurately recognize and relay to the jury," such as "machines or procedures which analyze physical data."

Lower court opinions applying *McDonald* make clear that the *Frye* rule could not be applied to exclude petitioners' expert testimony under California

California that has ruled on the substantive issue decided in *Oxendine*, petitioners are prepared to argue below that the California courts would reach the same substantive result as *Oxendine*. Surely, the courts below have not held otherwise; they have not even *looked* at California law. *See* pp. 49-50 n.76, *infra*.

That the *Frye* rule profoundly affects substantive rights has significance for two aspects of this case. First, it wholly vitiates any effort to vindicate *Frye* as a judge-made rule that stands independently of the Federal Rules of Evidence in diversity cases. For, bereft of the sanction of congressional authorization, the *Frye* rule's substantive impact dooms it under *Erie* jurisprudence. *See, e.g.*, *Hanna v. Plumer*, 380 U.S. 460, 469-70, 472 (1965); *Byrd v. Blue Ridge Rural Electric Cooperative, Inc.*, 356 U.S. 525, 536-37 (1958); *Bernhardt v. Polygraphic Co.*, 350 U.S. 198, 202-05 (1956); *Palmer v. Hoffman*, 318 U.S. 109, 117 (1943). See especially *Guaranty Trust Co. v. York*, 326 U.S. 99, 108-110 (1945) (refusing to apply a judicially developed doctrine in the context of diversity litigation in view of the impact of that doctrine on litigant

---

law. For example, a California appellate court recently overturned a trial court's use of *Frye* to exclude the opinion of an expert who said that a defendant accused of violent actions had suffered from "confusional arousal syndrome." *People v. Cegers*, 7 Cal.App.4th 988, 995 (Cal. Ct. App. 1992), *review denied*, 1992 Cal. App. LEXIS 4974 (Oct. 1, 1992). Even though the expert's "diagnosis was relatively new to medical science," *Frye* simply did not apply to this "stock medical testimony, subject on cross-examination to probing and on rebuttal to opposition expert evidence," for "[t]his was not a case in which a magical device was unveiled to astound a gullible jury." *Id.* at 304-05. California appellate courts have ruled that expert medical testimony on the cause of an injury cannot be subjected to the *Frye* rule, even where such testimony is novel and unsupported by published scientific studies. *See People v. Pitts*, 223 Cal.App.3d 606, 865 (1990) ("there is a difference between development of a new scientific technique — a novel method of proof — and development of a body of medical knowledge and expertise. . . . The expression of an expert medical opinion as to the cause of a wound or injury falls outside of the realm of what is subject to the *Kelly-Frye* rule") (citation omitted); *McCleery v. City of Bakersfield*, 170 Cal.App.3d 1059, 1071 (1985) (applying *McDonald* rule to admit scientific opinions even though "the proffered testimony in the instant case was novel — the trial court characterized appellants' efforts as 'trying to plow new ground in this case' — and was not backed by extensive scientific literature and scholarly studies as was the proffered testimony in *McDonald*").

and state interests).

Second, the substantive effect of the *Frye* rule in diversity cases also militates strongly against interpreting the Federal Rules of Evidence as incorporating the *Frye* rule. Congress has power to enact preemptive federal tort law that prescribes the quantum of proof required before drug manufacturers are held liable. But there is not the slightest evidence that Congress had any such intention when it enacted the Federal Rules of Evidence. This Court has long held that given the state interests recognized in *Erie* and the Rules of Decision Act, federal statutes and rules should be construed if at all possible to avoid a conflict with those interests. *See, e.g.*, *Hanna*, *supra*, 380 U.S. at 470 (finding an "unavoidable" clash given federal rule of "unmistakable clarity"); *Bernhardt*, *supra*, 350 U.S. at 200-02 (construing federal arbitration statute narrowly to avoid conflict); *Palmer v. Hoffman*, 318 U.S. 109, 117 (1943) (construing Fed. R. Civ. P. 8(c) narrowly to avoid conflict).[72] This practice is in keeping with the general rule of our federal system that Acts of Congress are to be construed "in light of the presumption against the pre-emption of state police power regulations." *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2618 (1992); *see also Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Furthermore, in order for the political safeguards of federalism to function effectively, *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528 (1985); *Gregory v. Ashcroft*, 111 S. Ct. 1069 (1991), the States must be put on notice about how much of their law is being removed by Congress. "Mere silence . . . cannot suffice to establish a clear and manifest purpose to pre-empt local authority." *Wisconsin Public Intervenor v.*

---

[72] The force of this policy is vividly illustrated by two unanimous decisions of this Court reaching opposite constructions of the same rule. *Compare Walker v. Armco Steel Corp.*, 446 U.S. 740, 750 (1980) (avoiding construction that, under Fed. R. Civ. P. 3, filing of complaint tolls statute of limitations for state-law actions, where state law requires effectuation of service) *with West v. Conrail*, 481 U.S. 35, 39 & n.4 (1987) (holding that under Rule 3, filing of complaint tolls statute of limitations for federal-law actions, and explaining opposite result in *Walker* as flowing from "[r]espect for the State's substantive decision that actual service is a component of the policies underlying the statute of limitations").

Mortier, 111 S. Ct. 2476, 2483 (1991).

Such an approach is all the more warranted here, for, as we have seen, Congress expressly exempted diversity suits from the scope of those evidence Rules that were thought likely to impact on state substantive law. *See* pp. 41-42, *supra*.[73] Had Congress thought that the Federal Rules of Evidence contained the *Frye* rule, it undoubtedly would have included a similar exemption of diversity suits. The absence of such an exemption is further confirmation that Congress did not believe it was enacting *Frye*.[74]

---

[73] Congress was so meticulous in safeguarding federalism values that "[a] study of the enacted Rules reveals little remaining that could plausibly have been attacked, were it subject to the Enabling Act's limitation, as modifying state substantive rights in diversity cases," confirming that Congress was "deeply concerned with preventing the undercutting of state substantive policy." Wellborn, *supra*, 55 Tex. L. Rev. at 401-02 & n.177. That inference follows especially in the context of this products liability suit, for Congress has traditionally been extremely reluctant to interfere with state law in tort cases. *See, e.g., Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984); *see generally* Gottesman, *Draining the Dismal Swamp: The Case for Federal Choice of Law Statutes*, 80 Georgetown L.J. 1, 30-31 (1991).

[74] The framers of the Rules were doubtless aware in 1975 that *Frye* up to then had been exclusively a criminal law evidence doctrine, devised initially under common law and later applied under Fed. R. Crim. P. 26. *See* p. 24 and note 50, *supra*. *Frye* was never applied by a federal appellate court to exclude evidence in a civil case until 1984. *See Barrel of Fun, Inc. v. State Farm Fire & Cas. Co.*, 739 F.2d 1028, 1031 (5th Cir. 1984). To achieve the goal of uniform rules of evidence for criminal and civil cases, *see* Rule 1101(b), the framers were required to choose between writing rules that would bring an end to *Frye* in criminal cases, or rules that would extend *Frye* to civil cases. Construing the Rules as effecting the first option is fully consistent with the "liberal thrust of the Federal Rules" with regard to opinion testimony, *Beech Aircraft*, *supra*, 488 U.S. at 169, and with this Court's *Erie* jurisprudence.

II. EVEN IF *FRYE* SURVIVES, ITS PROPER APPLICATION CANNOT TURN ON WHETHER THE EXPERT'S OPINION HAS BEEN PREVIOUSLY PUBLISHED IN A PEER-REVIEWED JOURNAL

The decision below did not rest with mandating use of *Frye*; it gave *Frye* a new and startling twist. As earlier recounted, plaintiffs' experts here consulted the data sources that scientists customarily rely upon to make findings respecting causation. The use of those data sources surely has "general acceptance" in the field. That is all that the *Frye* rule was ever designed to assure. It excluded testimony when "the thing from which the deduction is made" has not gained general acceptance (there a crude lie detector); so, too, *Frye*'s progeny involved conclusions drawn by experts from new forensic techniques. *See* pp. 16-17, *supra*; note 71, *supra*.

In contrast to such novel techniques, the route by which plaintiffs' experts arrived at their conclusions was through a standard technique in the field — by reanalyzing the epidemiological studies previously conducted by others. The court below did not suggest that such reanalysis is *not* a generally accepted practice in the field; indeed, it implicitly acknowledged that it is (and nothing in the record would support a contrary holding). Instead, the court below construed the *Frye* rule to render the evidence inadmissible because the particular conclusions that plaintiffs' experts derived from that reanalysis of the customary data sources had not been published in a peer-reviewed journal prior to their testifying:

> Plaintiffs argue that reanalysis is a generally accepted scientific technique, so it follows that their experts were basing their opinions on a permissible methodology. But the reanalysis of epidemiological studies is generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field . . . . Plaintiffs' reanalyses do not comply with this standard; they were unpublished, not subject to use in litigation.

J.A. 240-41.

The obligation of publication in such journals, and the concomitant delegation of substantial authority over admission of evidence in federal trials to the private editors of these journals, has no conceivable basis in law. "[T]he Federal Rules of Evidence contain no requirement that an expert's testimony be based upon reasoning subjected to peer-review and published in the professional literature." *DeLuca*, *supra*, 911 F.2d at 954. Indeed, in the vast majority of cases in which experts testify, they proffer opinions about factual issues without having previously published their opinions and without drawing upon the published reasoning of others who have addressed that precise factual issue. Their "peer review" comes when experts called by the other party, or appointed by the Court pursuant to Rule 706, mount the witness stand.

To be sure, that an expert's opinion has not been published in a peer-reviewed journal can be cited by the opposing party as bearing upon its persuasiveness. But the ultimate determination of the persuasiveness of an expert's opinion has been entrusted by the Federal Rules to the jurors, *Barefoot v. Estelle*, *supra*, not the editors of private journals nor even judges who wish to defer to such editors. The peer-review process has many virtues but, as explained in the margin, screening the reliability of experts' views for use in federal court is not among them, for neither the objectives of peer review nor its procedures are suited to the determination of truth.[75]

---

[75] The editor-in-chief of the New England Journal of Medicine and a former editor of the Journal of the American Medical Association both have disclaimed that peer review is an appropriate mechanism for determining the truth of experts' opinions. L.A. Times, May 22, 1989, Pt. II, at 3 col. 1 ("[p]eer review is far from being a 'perfect sausage machine for grinding out the truth'" (Dr. Arnold S. Relman); "the peer review process is 'not meant to determine ultimate truth or falsity.' [I]ts main functions [are] 'to improve the quality of what is published' and 'to help editors decide what they want to publish in their journals) (Elizabeth Knoll)). Moreover, the peer-reviewed journals in the fields pertinent to toxic tort causation depend heavily for income upon the advertising of drug companies. Lawrence K. Altman, *Study Says Drug Ads in Medical Journals Frequently Mislead*, N.Y. Times, June 1, 1992, at A1, col. 1 ("In 1991, drug companies spent $351 million on advertisements in medical journals"). The combined effect of all these influences is reflected in a *New York Times*-article which spotlighted a five-year delay in publication of a dissenting "re-analysis" of the efficacy of a frequently prescribed drug, resulting from "academia's surprising aversion to dissent," "the strong ties between scientific journals, academia and the drug industry," and "professional jealousies." *See Hidden Discord Over Right Therapy*, N.Y. Times, Dec. 24, 1991, at B6 col. 1. *See also* Charles W. McCutchen, *Peer Review: Treacherous Servant, Disastrous Master*, Technology Review, Oct. 1991, at 28, 30, 33; Jonathan Schlefer, *Truth, Beauty, and Peer Review*, Technology Review, Oct. 1990, at 5; Lawrence K. Altman, M.D., *The Doctor's World: Peer Review is Challenged*, N.Y. Times, Feb. 25, 1986, at C3 col. 1.

The bizarre "publish or perish" edict for expert testimony issued by the court below is both bad law and bad science, and at least raises ground for constitutional concern. Even if the peculiarly judicial function of deciding on the admissibility of trial evidence could be delegated to a private entity, *cf. Mistretta v. United States*, 488 U.S. 361, 373 n.7 (1989), this effective delegation of decisions on admissibility to private journalists funded in part by parties to litigation hardly safeguards petitioners' right to "an impartial and disinterested tribunal" for decision of their claims. *Joint Anti-Fascist Committee v. McGrath*, 341 U.S. 123, 172 (1951) (Frankfurter, J., concurring). By declining to construe the Federal Rules of Evidence as requiring peer-reviewed publication as the precondition to testimony, this Court can avoid these constitutional concerns in addition to the manifest *Erie* problems. *Siler v. Louisville & Nashville R. Co.*, 213 U.S. 175, 193 (1909).

* * *

Petitioners have demonstrated that the courts below erred by granting summary judgment on the basis that plaintiffs' evidence was rendered inadmissible by the *Frye* rule. Whether there be other grounds for excluding the evidence is a question not addressed below, and one that in the first instance is for the district court. Assuming that the evidence is admissible, the question whether it has sufficient weight to preclude a grant of summary judgment is, in this diversity case, a question of state law; for as shown *supra* pp. 42-44, it is for the state to determine what quantum of proof is needed to establish causation. To this point, neither of the courts below has consulted California law; rather, believing the issue to be one of admissibility of evidence, they have consulted only the decisions of federal courts in other circuits.[76] The determination

---

[76] In the words of the district court, it is "unfortunate[] for the plaintiffs" that their position is contrary to the "school[] of thought" "prevailing in the federal courts." (J.A. 229). The court of appeals' analysis begins: "Whether Bendectin is responsible for limb reduction defects is not a new

of state law is also a question for initial consideration by the district court. *Salve Regina College v. Russell*, 111 S. Ct. 1217, 1221-22 (1991).

CONCLUSION

For the reasons stated above, petitioners urge that the judgment below be reversed, and remanded with directions that all remaining questions respecting the summary judgment motion be addressed in the first instance by the district court.

Respectfully submitted,

DAVID L. SHAPIRO
1525 Massachusetts Avenue
Cambridge, MA 02138

KENNETH J. CHESEBRO
Counsel of Record
JONATHAN S. MASSEY
1600 Massachusetts Avenue
Cambridge, MA 02138
(617) 661-4423

MICHAEL H. GOTTESMAN
Georgetown Univ. Law Center
600 New Jersey Avenue, N.W.
Washington, D.C. 20001

MARY F. GILLICK
RICHARD S. SPIRRA
LUCE, FORWARD,
HAMILTON & SCRIPPS
600 West Broadway
San Diego, CA 92101

BARRY J. NACE
PAULSON, NACE, NORWIND
& SELLINGER
1814 "N" Street, N.W.
Washington, D.C. 20036

Counsel for Petitioners

December 2, 1992

---

question in the federal courts" (J.A. 239) and ends by embracing the holdings of other federal circuits. (J.A. 241). Neither opinion cites a single decision of a California court, or recognizes that there is a state law issue to decide.

APPENDIX TO BRIEF OF PETITIONER

STATUTORY AND CONSTITUTIONAL PROVISIONS

FEDERAL RULES OF EVIDENCE

Rule 104. Preliminary Questions

(a) Questions of admissibility generally. Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

(b) Relevancy conditions on fact. When the relevancy of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition.

[Amended effective October 1, 1987]

Rule 401. Definition of "Relevant Evidence"

"Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.

Rule 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible

All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Rule 403. Exclusion of Relevant Evidence on Grounds of Prejudice, Confusion, or Waste of Time

Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

Rule 501. General Rule

Except as otherwise required by the Constitution of the United States or provided by Act of Congress or in rules prescribed by the Supreme Court pursuant to statutory authority, the privilege of a witness, person, government, State, or political subdivision thereof shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and expeience. However, in civil actions and proceedings, with respect to an element of a claim or defense as to which State law supplies the rule of decision, the privilege of a witness, person, government, State, or political subdivision thereof shall be determined in accordance with State law.

Rule 602. Lack of Personal Knowledge

A witness may not testify to a matter unless evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter. Evidence to prove personal knowledge may, but need not, consist of the witness' own testimony. This rule is subject to the provisions of rule 703, relating to opinion testimony by expert witnesses.
[Amended effective October 1, 1987; November 1, 1988.]

Rule 701. Opinion Testimony by Lay Witnesses

If the witness is not testifying as an expert, the witness' testimony in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness and (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue.
[Ammended effective October 1, 1987]

Rule 702. Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Rule 703. Bases of Opinion Testimony by Experts

Tre facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.
[Amended effective October 12, 1984]

Rule 704. Opinion on Ultimate Issue

(a) Except as provided in subdivision (b), testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.

(b) No expert witness testifying with respect to the mental state or condition of a defendant in a criminal case may state an opinion or inferece as to whether the defendant did or did not have the mental state or condition constituting an element of the crime charged or of a defense thereto. Such ultimate issues are matters for the trier of fact alone.
[Amended effective October 12, 1984]

Rule 705. Disclosure of Facts or Data Underlying Expert Opinion

The expert may testify in terms of opinion or inference and gives reasons therefor without prior disclosure of the underlying facts or data, unless the court requires otherwise. The expert may in any event be required to disclose the underlying facts or data on cross-examination.
[Amended effective October 1, 1987]

Rule 706. Court Appointed Experts

(a) Appointment. The court may on its own motion or on the motion of any party enter an order to show cause why expert witnesses should not be appointed, and may request the parties to submit nominations. The court may appoint any expert witnesses agreed upon by the parties, and may appoint witnesses of its own selection. An expert witness shall not be appointed by the court unless the witness consents to act. A witness so appointed shall be informed of the witness' duties by the court in writing, a copy of which shall be filed with the clerk, or at a conference in which the parties shall have opportunity to participate. A witness so appointed shall advise the parties of the witness' findings, if any; the witness' deposition may be taken by any party; and the witness may be called to testify by the court or any party. The witness shall be subject to cross-examination by each party, including a party calling the witness.

(b) Compensation. Expert witnesses so appointed are entitled to reasonable compensation in whatever sum the court may allow. The compensation thus fixed is payable from funds which may be provided by law in criminal cases and civil acions and proceedings involving just compensation under the Fifth Amendment. In other civil cases the compensation shall be paid by the parties in such proportion and at such time as the court directs, and thereafter charged in like manner as other costs.

(c) Disclosure of appointment. In the exercise of its discretion, the court may authorize disclosure to the jury of the fact that the court appointed the expert witness.

(d) Parties' experts of own selection. Nothing in this rule limits the parties in calling expert witnesses of their own selection.
[Amended effective October 1, 1987]

Rule 803. Hearsay Exceptions; Availability of Declarant Immaterial

The following are not excluded by the hearsay rule, even though the declarant is available as a witness:

...

(18) Learned Treatises

To the extent called to the attention of an expert witness upon cross-examination or relied upon by the expert witness in direct examination, statments contained in published treatises, periodicals, or pamphlets on a subject of history , medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. If admitted, the statements may be read into evidence but may not be received as exhibits.

(24) Other Exceptions

A statement not specifically covered by any of the foregoing exceptions but having equivalent circumstantial guarantees of trustworthiness, if the court determines that (A) the statement is offered as evidence of a material fact; (B) the statement is more probative on the point for which it is offered than any other evidence for which the proponent can procure through reasonable efforts; and (C) the general purposes of these rules and the interests of justice will best be served by admission of the statement into evidence. However, a statement may not be admitted under this exception unless the proponent of it makes known to the adverse party sufficiently in advance of the trial or hearing to provide the adverse party with a fair opportunity to prepare to meet it, the proponent's intention to offer the statement and the particulars of it,

including the name and address of the declarant.
[Amended December 12, 1975; amended effective October 1, 1987.]

Rule 804. Hearsay Exceptions; Declarant Unavailable

(b) Hearsay Exceptions.

(5) Other Exceptions

A statement not specifically covered by any of the foregoing exceptions but having equivalent circumstantial guarantees of trustworthiness, if the court determines that (A) the statement is offered as evidence of a material fact; (B) the statement is more probative on the point for which it is offered than any other evidence which the proponent can procure through reasonable efforts; and (C) the general purposes of these rules and the interests of justice will best be served by admission of the statement into evidence. However, a statement may not be admitted under this exception unless the proponent of it makes known to the adverse party sufficiently in advance of the trial or hearing to provide the adverse party with a fair opportunity to prepare to meet it, the proponent's intention to offer the statement and the particulars of it, including the name and address of the declarant.
[Amended December 12, 1975; amended effective October 1, 1987; November 18, 1988.]

OTHER STATUTORY PROVISIONS

28 U.S.C. § 2071 (1988) provides, in relevant part:

§ 2071. Rule-making power generally

(a) The Supreme Court and all courts established by Act of Congress may from time to time prescribe rules for the conduct of their business. Such rules shall be consistent with Acts of Congress and rules of practice and procedure prescribed under section 2072 of this title.

(b) Any rule prescribed by a court, other than the Supreme Court, under subsection (a) shall be prescribed only after giving appropriate public notice and an opportunity for comment. Such rule shall take effect upon the date specified by the prescribing court and shall have such effect on pending proceedings as the prescribing court may order.

28 U.S.C. § 2072 (1988) provides, in relevant part:

§ 2072. Rules of procedure and evidence; power to prescribe.

(a) The Supreme Court shall have the power to prescribe general rules of practice and procedure and rules of evidence for cases in the United States district courts (including proceedings before magistrates thereof) and courts of appeals.

(b) Such rules shall not abridge, enlarge or modify any substantive right. All laws in conflict with such rules shall be of no further force and effect after such rules have taken effect.

The Rules of Decision Act, 28 U.S.C. § 1652 (1988) provides, in relevant part:

§ 1652. State laws as rules of decision.

The laws of the several states, except where the Constitution or treaties of the United States or Acts of Congress otherwise require or provide, shall be regarded as rules of decision in civil actions in the courts of the United States, in cases where they apply.